

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GUILLERMO MARTI and FELICIA MARTI
JT TEN, derivatively on behalf of SPERO
THERAPEUTICS, INC.,

Plaintiff,

vs.

ANKIT MAHADEVIA, SATYAVRAT
SHUKLA, MILIND DESHPANDE, JEAN-
FRANÇOIS FORMELA, SCOTT JACKSON,
JOHN C. POTTAGE, JR., CYNTHIA SMITH,
FRANK E. THOMAS, and PATRICK VINK,

Defendants,

and

SPERO THERAPEUTICS, INC.,

Nominal Defendant.

C.A. No.

JURY TRIAL DEMANDED

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

INTRODUCTION

Plaintiffs Guillermo Marti and Felicia Marti JT Ten (“Plaintiffs”), by Plaintiffs’ undersigned attorneys, derivatively and on behalf of Nominal Defendant Spero Therapeutics, Inc. (“Spero” or the “Company”), file this Verified Shareholder Derivative Complaint against Ankit Mahadevia (“Mahadevia”), Satyavrat Shukla (“Shukla”), Milind Deshpande (“Deshpande”), Jean-François Formela (“Formela”), Scott Jackson (“Jackson”), John C. Pottage, Jr. (“Pottage”), Cynthia Smith (“Smith”), Frank E. Thomas (“Thomas”), and Patrick Vink (“Vink”) (collectively, the “Individual Defendants,” and together with Spero, the “Defendants”) for breaches of their fiduciary duties as directors and/or officers of Spero, unjust enrichment, gross mismanagement, abuse of control, waste of corporate assets, violations of Section 14(a) of the Securities Exchange

Act of 1934 (the “Exchange Act”), and against Defendants Mahadevia and Shukla for contribution under Sections 10(b) and 21D of the Exchange Act. As for Plaintiffs’ complaint against the Defendants, Plaintiffs allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs’ own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs’ attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Spero, legal filings, news reports, securities analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Spero’s directors and officers from September 8, 2020 through May 3, 2022 (the “Relevant Period”).

2. Spero is a Delaware corporation based in Cambridge, Massachusetts. Spero describes itself as “a multi-asset, clinical-stage, biopharmaceutical company focused on identifying, developing and commercializing novel treatments for bacterial infections, including multi-drug resistant (‘MDR’) bacterial infections, and rare diseases.”

3. During the Relevant Period, the Company’s lead product candidate was tebipenem pivoxil hydrobromide (“Tebipenem HBr”), which is an oral carbapenem used to treat complicated urinary tract infections (“cUTIs”) and acute pyelonephritis. Spero sought approval from the United States Food and Drug Administration (“FDA”) for Tebipenem HBr for use in pill form as an anti-

bacterial medication in an effort to offer an easier and cheaper alternative to the onerous, already-FDA approved ertapenem drug, which is administered intravenously.

4. Spero began work on Tebipenem HBr years before the beginning of the Relevant Period. On October 20, 2017, Spero announced the launch of a Phase 1 trial focusing on safety and tolerability of Tebipenem HBr. In the announcement, the Company touted a “rapid development approach” for the drug candidate, stating that if Phase 1 produced positive results, Spero would quickly move to a single Phase 3 clinical trial. In the same announcement, Spero also reported that the FDA deemed Tebipenem HBr a Qualified Infectious Disease Product (“QIDP”) for cUTIs.

5. Less than a month later, on November 6, 2017, Spero held an initial public offering (“IPO”) on the NASDAQ Global Select Market (“NASDAQ GS”). The IPO injected approximately \$83.6 million into the Company. Throughout the IPO, Spero stressed the Company’s “rapid development approach” for Tebipenem HBr, especially the prospect of launching a Phase 3 clinical trial.

6. On February 4, 2019, the FDA accepted Spero’s Investigational New Drug (“IND”) application for Tebipenem HBr, which allowed Spero to deliver the drug candidate across state lines to clinical investigators for evaluation. In turn, Spero began patient enrollment in the United States for its “pivotal” global Phase 3 clinical trial (the “ADAPT-PO Trial”).

7. A little over a month later, on March 29, 2019, Spero announced the FDA had granted Tebipenem HBr Fast Track Designation, which spurs faster development and quickens the FDA’s evaluation of drug candidates meant for use in serious or life-threatening conditions that present the possible capability of meeting unmet medical needs. To facilitate successful Fast Track Designation, the FDA interacts more often with drug candidate companies than it normally would,

and also offers rolling review of the New Drug Application (“NDA”). In Spero’s case, the Company was given the opportunity to discuss the ADAPT-PO Trial with the FDA more often than normal and could do so in more detail.

8. By May 2020, Spero completed enrollment in the ADAPT-PO Trial, compiling a population of 1,372 patients. In an earnings press release issued on August 6, 2020, Spero informed investors that the Company expected to report top-line data from the ADAPT-PO Trial in the third quarter of 2020.

9. The Relevant Period begins on September 8, 2020, when Spero issued a press release that boasted about “positive” results in the ADAPT-PO Trial. Specifically, Spero reported that Tebipenem HBr was well tolerated, was similarly situated in its safety profile as the already FDA-approved intravenous (“IV”) ertapenem, and, importantly, reached the required threshold of a -12.5% non-inferiority (“NI”) margin as compared to ertapenem. In other words, with this press release, Spero signaled to investors that all signs were green for expedited FDA approval of Tebipenem HBr based on the data received in the ADAPT-PO Trial.

10. As Tebipenem HBr was Spero’s leading drug candidate at this time, investors and analysts were honing in on Spero’s public disclosures about Tebipenem HBr’s clinical progress. For example, several market analysts, including Cantor Fitzgerald, Oppenheimer, and Cowen, all had positive reactions to Spero’s September 8, 2020 announcement. Cantor Fitzgerald called it “clearly good news for SPRO” and further stated that “SPRO’s pipeline is underappreciated.” Oppenheimer called the ADAPT-PO Trial data “pristine.”

11. Just three days later, on September 11, 2020, the Individual Defendants issued a statement that announced the prices of a public offering of Spero common stock, seeking to sell 4.785 million common shares and 3.215 million shares of non-voting Series D Convertible

Preferred Stock for estimated total proceeds of \$80 million. On September 15, 2020, investors rewarded the Individual Defendants in the public offering. After the offering was completed that day, Spero received \$74.7 million in proceeds after offering and underwriting expenses.

12. During this time, Defendant Mahadevia publicly touted several “pre-NDA meetings” with the FDA. By March 2021, Spero publicly acknowledged that the Company held at least one pre-NDA meeting with the FDA during which “the format and content of the planned data package” of Tebipenem HBr’s NDA was discussed, and that Spero “received feedback” from the FDA during this meeting.

13. On May 6, 2021, Spero issued a press release announcing its operating results for the period ended March 31, 2021 and provided updates regarding the progress of Tebipenem HBr. Specifically, Defendant Mahadevia stated that Spero had a pre-NDA meeting with the FDA regarding Tebipenem HBr, and received feedback that the data provided was sufficient to support an NDA submission. Defendant Mahadevia also stated that Spero was on track to submit an NDA for Tebipenem HBr in the second half of 2021.

14. On August 5, 2021, Spero issued another press release announcing its operating results for the period ended June 30, 2021 and provided updates on the progress of Tebipenem HBr. Specifically, Defendant Mahadevia stated that the Company’s focus remained on progressing with Tebipenem HBr towards an NDA filing.

15. By September 2021, Defendant Mahadevia publicly touted that Spero had “multiple” discussions with the FDA pertaining to whether data from the ADAPT-PO Trial could support an NDA for Tebipenem HBr.

16. On October 28, 2021, Spero issued a press release announcing its submission of the Tebipenem HBr NDA to the FDA. Specifically, Defendant Mahadevia stated that the submission

of the NDA was a major step towards the Company's goal and that, if approved, would allow Tebipenem HBr to help many patients suffering from cUTIs and acute pyelonephritis and reduce healthcare resource utilization overall.

17. On November 10, 2021, Spero issued a press release announcing its operating results for the period ended September 30, 2021 and provided updates regarding the Tebipenem HBr NDA. Specifically, Defendant Mahadevia stated that the Tebipenem HBr NDA had been submitted to the FDA and was pending FDA approval. He indicated that Spero was anticipating a commercial release for Tebipenem HBr in the second half of 2022.

18. On the same day, during an earnings call with investors, Defendant Mahadevia provided insight into the type of data included in the NDA package submitted to the FDA for Tebipenem HBr. He stated that the positive data set from the ADAPTO-PO Trial was a key portion of the data provided in the NDA and that his previous discussions with the FDA indicated that positive results from well-controlled pivotal trials such as the ADAPT-PO Trial had been sufficient to support NDA approval for other drug candidates.

19. On January 3, 2022, Spero announced in a press release that the FDA had granted the Tebipenem HBr NDA Priority Review and Fast Track designations. Defendant Mahadevia stated that the FDA's acceptance of the Tebipenem HBr was a major accomplishment and that the Company would be committed to working with the FDA throughout the review process.

20. However, unknown to investors and the public, due to deficiencies with Tebipenem HBr's NDA and clinical data related to the ADAPT-PO Trial, Spero's NDA was not on track for FDA approval. Specifically, and contrary to Spero's public statements, the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable and failed to

generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval.

21. Indeed, Plaintiffs' counsel in the Securities Class Action (defined below) interviewed six former employees of Spero (the "CWs"), who noted that between December 2021 and February 2022, the FDA contacted Spero an abnormally high number of times, inquiring about the ADAPT-PO Trial's "clinical" data "a couple of times a week."

22. The truth began to emerge on March 31, 2022, after the market closed, when Spero announced through a press release that the FDA notified the Company "that, as part of its ongoing review of Spero's New Drug Application (NDA) for tebipenem HBr, it has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time."

23. On this news, the Company's stock price fell \$1.59 per share, or 18.27%, from closing at \$8.70 per share on March 31, 2022, to closing at \$7.11 per share on April 1, 2022 on high trading volume.

24. Yet, Defendant Mahadevia attempted to mitigate the situation by publicly stating and internally maintaining that Spero could fix the identified deficiencies before Spero's Late Cycle Meeting ("LCM") with the FDA to be held near the end of April 2022. Defendants went to great lengths to conceal the unfortunate truth from Spero's own employees, going so far as to prevent access to Spero's servers which held the ADAPT-PO Trial data.

25. The truth fully emerged on May 3, 2022 when Spero announced, through another press release, "that it will immediately defer current commercialization activities for tebipenem HBr based on feedback from a recent Late Cycle Meeting (LCM) with the U.S. Food and Drug Administration (FDA) regarding Spero's New Drug Application (NDA) for tebipenem HBr[.]" and that, "[a]lthough the review is still ongoing and the FDA has not yet made any final

determination regarding approvability, the discussion suggested that the data package may be insufficient to support approval during this review cycle.”

26. Spero announced that the FDA cut the population of evaluable patients in the ADAPT-PO Trial down by excluding the gram-positive patients, causing “the pre-specified non-inferiority (NI) margin of - 12.5%” to be missed.

27. The press release also revealed that “[i]n connection with this development, Spero announced that it is *undertaking a reduction in its workforce by approximately 75%* and a restructuring of its operations to reduce operating costs and reallocate resources.”

28. Spero followed through with this announcement just five days later, dispatching 75% of the Company’s employees with severance payments. Several of the CWs interviewed in the Securities Class Action were stunned by the layoffs and indicated that the workforce reduction must have been planned far in advance of its announcement given its sheer size and swift execution.

29. On this news, the Company’s stock price plummeted \$3.24 per share, or 63.65%, from closing at \$5.09 per share on May 2, 2022, to close at \$1.85 per share on May 3, 2022.

30. Throughout the Relevant Period, the investing public was under a false impression of the Company’s business, operations, financial success, and growth. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements to the investing public that failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval; (3) Spero faced an unusually high amount of questions and inquiries from the FDA before and

after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company's workforce and a shift in the Company's focus; (6) due to the foregoing, Spero's reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed to maintain adequate internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

31. The Individual Defendants also breached their fiduciary duties by failing to correct and/or caused the Company to fail to correct these false and misleading statements and omissions of material fact to the investing public.

32. Additionally, in breach of their fiduciary duties, the Individual Defendants willfully or recklessly caused the Company to fail to maintain adequate internal controls while one of the Defendants engaged in improper insider sales, netting personal proceeds of \$471,518.

33. In light of the Individual Defendants' misconduct—which has subjected the Company, its Chief Executive Officer ("CEO"), its former CEO, and its former Chief Financial Officer ("CFO") to being named as defendants in a federal securities fraud class action lawsuit pending in the United States District Court for the Eastern District of New York (the "Securities Class Action"), and which has further subjected the Company to the need to undertake internal investigations, the need to implement adequate internal controls, losses from the waste of corporate assets, and losses due to the unjust enrichment of Individual Defendants who were improperly overcompensated by the Company and/or who benefitted from the wrongdoing alleged herein—the Company will have to expend many millions of dollars.

34. Moreover, in light of the breaches of fiduciary duty engaged in by the Individual Defendants, most of whom are the Company's current directors, their collective engagement in fraud, the substantial likelihood of the directors' liability in this derivative action and Defendant Mahadevia's and Defendant Shukla's liability in the Securities Class Action, their being beholden to each other, their longstanding business and personal relationships with each other, and their not being disinterested and/or independent directors, a majority of Spero's Board of Directors (the "Board") cannot consider a demand to commence litigation against themselves and the other Individual Defendants on behalf of the Company with the requisite level of disinterestedness and independence.

JURISDICTION AND VENUE

35. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiffs' claims raise a federal question under Section 11(f) of the Securities Act, 15 U.S.C. § 77k(f)(1), Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1)), Rule 14a-9 of the Exchange Act, 17 C.F.R. § 240.14a-9, and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), and raise a federal question pertaining to the claims made in the Securities Class Action based on violations of the Exchange Act.

36. This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367(a).

37. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

38. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401 because a substantial portion of the transactions and wrongs complained of herein occurred in this District,

and the Defendants have received substantial compensation in this District by engaging in numerous activities that had an effect in this District.

PARTIES

Plaintiffs

39. Plaintiffs are current shareholders of Spero. Plaintiffs have continuously held Spero common stock since the time of the alleged wrongdoing.

Nominal Defendant Spero

40. Nominal Defendant Spero is a Delaware corporation with its principal executive offices located at 675 Massachusetts Avenue 14th Floor, Cambridge, MA 02139. Spero's shares trade on the NASDAQ GS under the ticker symbol "SPRO."

Defendant Mahadevia

41. Defendant Mahadevia currently serves as the Chairman of the Board and has served as a Company director since September 2013. He previously served as the Company's CEO and President from March 2015 until he "stepped down" on August 1, 2023. According to the Company's proxy statement filed on Schedule 14A with the SEC on September 1, 2023 (the "2023 Proxy Statement"), as of August 11, 2023, Defendant Mahadevia beneficially owned 1,280,837 shares of the Company's common stock, representing 2.38% of the Company's total outstanding stock as of that date. Given that the price per share of the Company's stock at the close of trading on August 11, 2023 was \$1.40, Defendant Mahadevia beneficially owned approximately \$1,793,172 worth of Spero stock.

42. For the fiscal year ended December 31, 2020 (the "2020 Fiscal Year"), Defendant Mahadevia received \$2,120,788 in total compensation from the Company. This included \$536,667 in salary, \$1,153,962 in option awards, \$424,049 in non-equity incentive plan compensation, and \$6,110 in all other compensation. For the fiscal year ended December 31, 2021 (the "2021 Fiscal

Year”), Defendant Mahadevia received \$4,875,045 in total compensation from the Company. This included \$590,417 in salary, \$1,300,000 in stock awards, \$2,650,765 in option awards, \$327,618 in non-equity incentive plan compensation, and \$6,245 in all other compensation. For the fiscal year ended December 31, 2022 (the “2022 Fiscal Year”), Defendant Mahadevia received \$4,239,705 in total compensation from the Company. This included \$633,750 in salary, \$254,000 in bonuses, \$1,499,998 in stock awards, \$1,499,998 in option awards, \$342,900 in non-equity incentive plan compensation, and \$9,733 in all other compensation.

43. During the period when the Company materially misstated information to the investing public to keep the stock price inflated, and before the scheme was exposed, Defendant Mahadevia made the following sales of Company stock at artificially inflated prices:

Date	Shares Sold	Avg. Price Per Share	Proceeds
September 8, 2020	774	\$14.25	\$11,029.70
October 13, 2020	14,367	\$14.28	\$205,212.50
October 14, 2020	105	\$14.25	\$1,496.30
October 23, 2020	20	\$14.25	\$285.00
November 3, 2020	2,137	\$14.26	\$30,489.60
November 4, 2020	7,370	\$14.42	\$106,335.10
December 27, 2021	8,000	\$14.58	\$116,640

Thus, in total, before the fraud was exposed, he sold 32,773 shares of Company common stock at artificially inflated prices on inside information, for which he received approximately \$471,518. His insider sales, made with knowledge of material nonpublic information before the material misstatements and omissions were exposed, demonstrate his motive in facilitating and participating in the scheme.

44. The Company's 2023 Proxy Statement stated the following about Defendant Mahadevia:

Ankit Mahadevia, M.D. has been a member of our Board of Directors since September 2013 and currently serves as Chairman of our Board of Directors, a position he has held since August 2023. Dr. Mahadevia formerly served as our Chief Executive and President from March 2015 until August 2023. He was formerly a Venture Partner in the life sciences group at Atlas Venture, located in Cambridge, Massachusetts. In that capacity, he supported the formation of eight companies focused on novel drug discovery platforms and therapeutic products, including Nimbus Therapeutics, Artea Therapeutics (acquired by Lilly), and Translate Bio (Nasdaq: TBIO). He led three of these companies as acting chief executive officer, including Synlogic (Nasdaq: SYBX). Prior to joining Atlas Venture in 2008, Dr. Mahadevia worked on product and business development with the founding team at Arcion Therapeutics, Inc. He has also held positions in business development both at Genentech, Inc. and at Vanda Pharmaceuticals Inc. Previously, he worked in the health care groups of McKinsey & Company and Monitor Group. Dr. Mahadevia began his career in health care policy, with roles in the U.S. Senate Health, Education, Labor, and Pensions committees, the U.S. Government Accountability Office and the Mexican Institute of Social Security. He has spoken widely on entrepreneurship, including at Harvard University, Columbia University, Northwestern University, and the Berkeley Forum. Dr. Mahadevia has also been active in the policy of life science innovation, including service on the Advisory Council at the NIH National Center for Advancing Translational Sciences. Dr. Mahadevia holds an M.D. from the Johns Hopkins School of Medicine, an M.B.A. from the Wharton School at the University of Pennsylvania and a B.A. in Economics and Biology from Northwestern University. We believe that Dr. Mahadevia is qualified to serve on our Board of Directors due to his experience serving as our Chief Executive Officer and President and his extensive experience in the life sciences industry.

Defendant Shukla

45. Defendant Shukla has served as the Company's CEO, President, and as a director since August 1, 2023. He previously served as the Company's CFO from January 2021 until August 1, 2023. According to the 2023 Proxy Statement, as of August 11, 2023, Defendant Shukla beneficially owned 79,742 shares of the Company's common stock. Given that the price per share of the Company's stock at the close of trading on August 11, 2023 was \$1.40, Defendant Shukla beneficially owned approximately \$111,639 worth of Spero stock.

46. For the 2021 Fiscal Year, Defendant Shukla received \$2,228,271 in total compensation from the Company. This included \$440,889 in salary, \$164,000 in bonuses, \$399,994 in stock awards, \$1,039,433 in option awards, \$175,660 in non-equity incentive plan compensation, and \$8,295 in all other compensation. For the 2022 Fiscal Year, Defendant Shukla received \$1,673,070 in total compensation from the Company. This included \$478,333 in salary, \$168,000 in bonuses, \$424,997 in stock awards, \$424,807 in option awards, \$172,800 in non-equity incentive plan compensation, and \$4,133 in all other compensation.

47. The Company's 2023 Proxy Statement stated the following about Defendant Shukla:

Satyavrat Shukla has served as our Chief Executive Officer and President since August 2023 and has been a member of our Board of Directors since August 2023. He formerly served as our Chief Financial Officer and Treasurer from January 2021 to August 2023. He has over 20 years of strategic and financial leadership experience. He was most recently Chief Financial Officer at Ziopharm Oncology, Inc. from July 2019 to December 2020, where he directed all of Ziopharm's financial aspects, including financial planning, analysis and reporting, treasury and tax functions, capital strategy and investor relations. Prior to Ziopharm, Mr. Shukla was Vice President and Global Head of Corporate Finance for Vertex Pharmaceuticals, Inc. from July 2012 to July 2019, where he managed financial planning, analysis and budgeting, and led the annual long-range planning process encompassing Vertex's entire portfolio and operations across more than 30 countries. Previously, Mr. Shukla was a Principal at Cornerstone Research, where he led teams providing consulting services for life science clients ranging from start-ups to multi-billion-dollar corporations. Prior to Cornerstone, he worked for finance consulting firms LECG Corporation and Putnam, Hayes & Bartlett, Inc. Mr. Shukla earned a B.A. in Economics from Harvard University and an M.B.A. in Finance and Strategy from Yale University. He also holds the Chartered Financial Analyst designation.

Defendant Deshpande

48. Defendant Deshpande has served as a Company director since January 2014. He previously served as Chairman of the Board from January 2014 until August 1, 2023. He also serves as Chair of the Nominating and Corporate Governance Committee and as a member of the

Compensation Committee. According to the 2023 Proxy Statement, as of August 11, 2023, Defendant Deshpande beneficially owned 115,118 shares of the Company's common stock. Given that the price per share of the Company's stock at the close of trading on August 11, 2023 was \$1.40, Defendant Deshpande beneficially owned approximately \$161,165 worth of Spero stock.

49. For the 2020 Fiscal Year, Defendant Deshpande received \$151,918 in total compensation from the Company. This included \$42,500 in fees earned or paid in cash and \$109,418 in option awards. For the 2021 Fiscal Year, Defendant Deshpande received \$150,892 in total compensation from the Company. This included \$42,500 in fees earned or paid in cash and \$108,392 in option awards. For the 2022 Fiscal Year, Defendant Deshpande received \$109,550 in total compensation from the Company. This included \$95,000 in fees earned or paid in cash and \$14,550 in stock awards.

50. The Company's 2023 Proxy Statement stated the following about Defendant Deshpande:

Milind Deshpande, Ph.D. has served on our Board of Directors since January 2014 and previously served as Chairman of our Board of Directors from January 2014 to August 2023. Dr. Deshpande is the President and Chief Executive Officer at Nayan Therapeutics since February 2019, and previously served as President and Chief Executive Officer of Avilar Therapeutics from January 2020 to June 2021. He is also a Venture Partner at RA Capital, where he has served since October 2018. Dr. Deshpande served as President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. and served on the board of directors from May 2013 until May 2018. He joined Achillion in September 2001 as Vice President of Chemistry, was named Head of Drug Discovery in April 2002, Senior Vice President of Drug Discovery in December 2002, Senior Vice President and Chief Scientific Officer in December 2004, Executive Vice President of Research and Chief Scientific Officer in June 2007 and President of Research and Development in October 2010. Prior to joining Achillion, Dr. Deshpande was Associate Director of Lead Discovery and Early Discovery Chemistry at the Pharmaceutical Research Institute at Bristol-Myers Squibb Co. from 1991 to 2001, where he managed the identification of new clinical candidates to treat infectious and neurological diseases. From 1988 to 1991, he held a faculty position at Boston University Medical School. Dr. Deshpande currently serves as the chairman of the board of directors of Avilar Therapeutics and as a member of the board of directors of Triana

Biomedicines and Clear Creek Bio. Dr. Deshpande received his Ph.D. in Organic Chemistry from Ohio University, following his undergraduate education in India. We believe that Dr. Deshpande is qualified to serve on our Board of Directors due to his extensive experience in the life sciences industry.

Defendant Formela

51. Defendant Formela served as a Company director from June 2017 to October 1, 2021. He also served as a member of the Compensation Committee and as a member of the Nominating and Corporate Governance Committee. According to the Company's proxy statement filed on Schedule 14A with the SEC on July 6, 2021 (the "2021 Proxy Statement"), as of June 1, 2021, Defendant Formela beneficially owned 2,425,682 shares of the Company's common stock, representing 8.17% of the total outstanding shares of the Company. 1,376,968 of the 2,425,682 shares are owned by Atlas Venture Associates IX, L.P, of which Defendant Formela is a member. Given that the price per share of the Company's stock at the close of trading on June 1, 2021 was \$14.68, Defendant Formela beneficially owned approximately \$35,609,012 worth of Spero stock as of that date.

52. For the 2020 Fiscal Year, Defendant Formela received \$118,418 in total compensation from the Company. This included \$9,000 in fees earned or paid in cash and \$109,418 in option awards. For the 2021 Fiscal Year, Defendant Formela received \$106,403 in total compensation from the Company. This included \$33,000 in fees earned or paid in cash and \$73,403 in option awards.

53. The Company's 2021 Proxy Statement stated the following about Defendant Formela:

Jean-François Formela, M.D. has served on our Board of Directors since March 2013. Dr. Formela is currently a partner at Atlas Venture and focuses on novel drug discovery approaches and therapeutics. He joined Atlas Venture in 1993 to build the U.S. life sciences franchise. He is a director and co-founder of IFM Therapeutics, Intellia Therapeutics (Nasdaq: NTLA), Korro Bio, Triplet

Therapeutics and Translate Bio (Nasdaq: TBIO). Jean-François also serves on the boards of F-star, Ikena Oncology and Scorpion Therapeutics. His prior investments include Adnexus, ArQule (Nasdaq: ARQL), Arteaus Therapeutics (acquired by Eli Lilly), CoStim Pharmaceuticals (acquired by Novartis), deCODE (Nasdaq: DCGN), Exelixis (Nasdaq: EXEL) and NxStage (Nasdaq: NXTM). Dr. Formela is a member of the Partners Healthcare Innovation Advisory Board and a former trustee of the Boston Institute of Contemporary Art. He received his M.D. from Paris University School of Medicine and his M.B.A. from Columbia University. We believe Dr. Formela's experience in the life sciences industry, as well as his practice of medicine, provides him with the qualifications and skills to serve as a director of our Company.

Defendant Jackson

54. Defendant Jackson has served as a Company director since April 2020. He also serves as a member of the Audit Committee and the Nominating and Corporate Governance Committee. According to the 2023 Proxy Statement, as of August 11, 2023, Defendant Jackson beneficially owned 45,000 shares of the Company's common stock. Given that the price per share of the Company's stock at the close of trading on August 11, 2023 was \$1.40, Defendant Jackson beneficially owned approximately \$63,000 worth of Spero stock.

55. For the 2020 Fiscal Year, Defendant Jackson received \$321,460 in total compensation from the Company. This included \$30,104 in fees earned or paid in cash and \$291,356 in option awards. For the 2021 Fiscal Year, Defendant Jackson received \$115,903 in total compensation from the Company. This included \$42,500 in fees earned or paid in cash and \$73,403 in option awards. For the 2022 Fiscal Year, Defendant Jackson received \$72,050 in total compensation from the Company. This included \$57,000 in fees earned or paid in cash and \$14,550 in stock awards.

56. The Company's 2023 Proxy Statement stated the following about Defendant Jackson:

Scott Jackson has served on our Board of Directors since April 2020. Mr. Jackson served as Chief Executive Officer and as a member of the

board of directors of Celator Pharmaceuticals, Inc. from April 2008 until July 2016, when the company was acquired by Jazz Pharmaceuticals plc. Mr. Jackson has more than thirty years of corporate leadership experience in the pharmaceutical and biotechnology industry and has held positions of increasing responsibility in sales, marketing and commercial development at Eli Lilly & Company, SmithKline Beecham plc, ImClone Systems Incorporated, Centocor Inc., a division of Johnson & Johnson, Eximias Pharmaceutical Corporation and YM BioSciences Inc. Mr. Jackson presently serves on the boards of Philabundance Food Bank, MacroGenics, Inc. and GlycoMimetics, Inc. Mr. Jackson holds a B.S. in pharmacy from the Philadelphia College of Pharmacy and Science and an M.B.A. from the University of Notre Dame. We believe that Mr. Jackson's extensive executive leadership experience in the pharmaceutical industry and his experience as a member of the board of directors of other publicly traded biotechnology companies, as well as his broad life sciences industry knowledge qualifies him to serve on our Board of Directors.

Defendant Pottage

57. Defendant Pottage has served as a Company director since September 2018. He also serves as a member of the Audit Committee. According to the 2023 Proxy Statement, as of August 11, 2023, Defendant Pottage beneficially owned 48,219 shares of the Company's common stock. Given that the price per share of the Company's stock at the close of trading on August 11, 2023 was \$1.40, Defendant Pottage beneficially owned approximately \$67,507 worth of Spero stock.

58. For the 2020 Fiscal Year, Defendant Pottage received \$126,926 in total compensation from the Company. This included \$52,500 in fees earned or paid in cash and \$74,426 in option awards. For the 2021 Fiscal Year, Defendant Pottage received \$125,903 in total compensation from the Company. This included \$52,500 in fees earned or paid in cash and \$73,403 in option awards. For the 2022 Fiscal Year, Defendant Pottage received \$74,550 in total compensation from the Company. This included \$60,000 in fees earned or paid in cash and \$14,550 in stock awards.

59. The Company's 2023 Proxy Statement stated the following about Defendant Pottage:

John C. Pottage, Jr., M.D. has served on our Board of Directors since September 2018. Dr. Pottage served as Senior Vice President and Chief Scientific and Medical Officer of ViiV Healthcare from November 2009 to October 2019. From September 2008 to November 2009, Dr. Pottage served as Senior Vice President, Head of Infectious Disease Medicine Development Center and, from June 2007 to September 2008, as the Vice President, Global Clinical Development of Antivirals, at GlaxoSmithKline. Prior to joining GlaxoSmithKline, Dr. Pottage served as Chief Medical Officer and Senior Vice President of Drug Development of Achillion Pharmaceuticals from May 2002 to May 2007. From July 1998 to May 2002, Dr. Pottage served as Medical Director of Vertex Pharmaceuticals (Nasdaq: VRTX) ("Vertex"). Dr. Pottage currently serves on the board of directors of Pardes Biosciences. We believe that Dr. Pottage's extensive industry and executive experience, his broad experience within the biopharmaceutical sector and his knowledge of the life sciences industry qualifies him to serve on our Board of Directors.

Defendant Smith

60. Defendant Smith has served as a Company director since March 2019. She also serves as a member of the Compensation Committee. According to the 2023 Proxy Statement, as of August 11, 2023, Defendant Smith beneficially owned 50,848 shares of the Company's common stock. Given that the price per share of the Company's stock at the close of trading on August 11, 2023 was \$1.40, Defendant Smith beneficially owned approximately \$71,187 worth of Spero stock.

61. For the 2020 Fiscal Year, Defendant Smith received \$114,426 in total compensation from the Company. This included \$40,000 in fees earned or paid in cash and \$74,426 in option awards. For the 2021 Fiscal Year Defendant Smith received \$113,392 in total compensation from the Company. This included \$5,000 in fees earned or paid in cash and \$108,392 in option awards. For the 2022 Fiscal Year, Defendant Smith received \$64,550 in total

compensation from the Company. This included \$50,000 in fees earned or paid in cash and \$14,550 in stock awards.

62. The Company's 2023 Proxy Statement stated the following about Defendant Smith:

Cynthia Smith has served on our Board of Directors since March 2019. Ms. Smith was Chief Commercial Officer of ZS Pharma, from June 2013 to December 2016. ZS Pharma became a subsidiary of AstraZeneca after its acquisition in December 2015. Prior to joining ZS Pharma, Ms. Smith was Vice President, Market Access & Commercial Development at Affymax, Inc., a biotechnology company focused on the development and commercialization of novel renal therapies, including a new anemia drug for chronic kidney disease patients. Ms. Smith was employed at Affymax from October 2008 to March 2013. Prior to Affymax, Ms. Smith was Executive Director of Healthcare Systems and Medicare Strategy at Merck. During her tenure at Merck from June 2000 to October 2008, she also held various leadership positions in corporate strategy, public policy, and external affairs, including global crisis management for the Vioxx recall. Before joining the pharmaceutical industry, she served in the White House Office of Management and Budget (OMB) in the Clinton Administration. Ms. Smith earned an M.B.A. from the Wharton School of the University of Pennsylvania, an MS in public policy from the Eagleton Institute of Politics at Rutgers University, and a BA from the University of North Carolina at Chapel Hill. Ms. Smith also serves on the boards of directors of Agios Pharmaceuticals, Akebia Therapeutics and Protara Therapeutics, Inc. We believe that Ms. Smith's extensive management experience in the healthcare industry and her experience as a member of the board of directors of other publicly traded biotechnology companies, as well as her broad life sciences industry knowledge, qualifies her to serve on our Board of Directors.

Defendant Thomas

63. Defendant Thomas has served as a Company director since June 2017. He also serves as Chair of the Audit Committee and as a member of the Nominating and Corporate Governance Committee. According to the 2023 Proxy Statement, as of August 11, 2023, Defendant Thomas beneficially owned 78,893 shares of the Company's common stock. Given that the price per share of the Company's stock at the close of trading on August 11, 2023 was \$1.40, Defendant Thomas beneficially owned approximately \$110,450 worth of Spero stock.

64. For the 2020 Fiscal Year, Defendant Thomas received \$128,422 in total compensation from the Company. This included \$36,500 in fees earned or paid in cash and \$91,922

in option awards. For the 2021 Fiscal Year, Defendant Thomas received \$127,391 in total compensation from the Company. This included \$36,500 in fees earned or paid in cash and \$90,891 in option awards. For the 2022 Fiscal Year, Defendant Thomas received \$82,066 in total compensation from the Company. This included \$47,500 in fees earned or paid in cash, \$14,550 in stock awards, and \$20,016 in option awards.

65. The Company's 2023 Proxy Statement stated the following about Defendant Thomas:

Frank E. Thomas has served on our Board of Directors since July 2017. Mr. Thomas is currently President and Chief Operating Officer of Orchard Therapeutics, a development-stage biotechnology company based in the United Kingdom, where he served as Chief Financial Officer and Chief Business Officer from January 2018 to March 2020. Prior to Orchard, Mr. Thomas served as the President and Chief Operating Officer of AMAG Pharmaceuticals, Inc., a commercial-stage pharmaceutical company, which was a publicly traded company that was subsequently acquired by Covis Pharma, from April 2015 to April 2017, as AMAG's Executive Vice President and Chief Operating Officer from May 2012 through April 2015 and as Executive Vice President, Chief Financial Officer and Treasurer from August 2011 through May 2012. Prior to AMAG, he served as Senior Vice President, Chief Operating Officer and Chief Financial Officer for Molecular Biometrics, Inc., a commercial-stage medical diagnostics company, from October 2008 to July 2011. Prior to Molecular Biometrics, Mr. Thomas spent four years at Critical Therapeutics, Inc., which was a publicly traded company that subsequently merged with Cornerstone Therapeutics Inc., from April 2004 to March 2008, where he was promoted to President in June 2006 and Chief Executive Officer in December 2006 from the position of Senior Vice President and Chief Financial Officer. He also served on the board of directors of Critical Therapeutics from 2006 to 2008. Prior to 2004, Mr. Thomas served as the Chief Financial Officer and Vice President of Finance and Investor Relations at Esperion Therapeutics, Inc., a public biopharmaceutical company (Nasdaq: ESPR). Mr. Thomas was a member of the board of directors of the Massachusetts Biotechnology Council from 2007 to 2015. Mr. Thomas currently serves as a member of the board of directors of Larimar Therapeutics Inc (Nasdaq: LRMR). Mr. Thomas holds a B.B.A. from the University of Michigan, Ann Arbor. We believe that Mr. Thomas' extensive commercial and operational management experience at biopharmaceutical companies and with financial matters qualifies him to serve on our Board of Directors.

Defendant Vink

66. Defendant Vink has served as a Company director since September 2015. He also serves as Chair of the Compensation Committee and as a member of the Audit Committee. According to the 2023 Proxy Statement, as of August 11, 2023, Defendant Vink beneficially owned 93,200 shares of the Company's common stock. Given that the price per share of the Company's stock at the close of trading on August 11, 2023 was \$1.40, Defendant Vink beneficially owned approximately \$130,480 worth of Spero stock.

67. For the 2020 Fiscal Year, Defendant Vink received \$126,918 in total compensation from the Company. This included \$17,500 in fees earned or paid in cash and \$109,418 in option awards. For the 2021 Fiscal Year, Defendant Vink received \$125,891 in total compensation from the Company. This included \$35,000 in fees earned or paid in cash and \$90,891 in option awards. For the 2022 Fiscal Year, Defendant Vink received \$84,566 in total compensation from the Company. This included \$50,000 in fees earned or paid in cash, \$14,550 in stock awards, and \$20,016 in option awards.

68. The Company's 2023 Proxy Statement stated the following about Defendant Vink:

Patrick Vink, M.D. has served on our Board of Directors since September 2015 and currently serves as our Lead Director, a position he has held since August 2023. Dr. Vink has been an advisor to the pharmaceutical industry since 2015 and board member of several companies. Previously, Dr. Vink was employed at Cubist Pharmaceuticals, Inc ("Cubist"). Most recently, he served as Executive Vice-President and Chief Operating Officer, overseeing all worldwide commercial and technical operations as well as global alliance management and managing the company's profit and loss. He joined Cubist in 2012 as Senior Vice President and Head of all International Business Operations. In this role, he was responsible for the business activities in International markets outside USA. Prior to joining Cubist, Dr. Vink served as Senior Vice President, Global Head of Hospital Business and Global Head of Biologics for Mylan Inc. In this role, Dr. Vink managed the global hospital business of the company. He joined Mylan in 2008 and established a number of global functions for the company in Switzerland. Before joining Mylan, Dr. Vink held several leadership positions across the industry, including Head of Global Business Franchise Biopharmaceuticals for Novartis Sandoz; Vice President International Business for Biogen, Inc.; and Head of Worldwide Marketing, Cardiovascular and Thrombosis for Sanofi-Synthélabo SA. Dr. Vink

served as a member of the Executive Committee of the European Federation of Pharmaceutical Industries and Associations (EFPIA) between 2013 and 2015. Dr. Vink graduated as a medical doctor from the University of Leiden, Netherlands in 1988 and obtained his M.B.A. in 1992 from the University of Rochester. Dr. Vink serves on the boards of directors of Santhera Pharmaceuticals AG, Amryt Pharma PLC., and is Chairman of the board of directors of two privately held companies. We believe that Dr. Vink is qualified to serve on our Board of Directors because of his extensive operational business experience, significant knowledge of the activities of our company, and diverse background serving on the board of directors of various public and private life science companies.

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

69. By reason of their positions as officers and/or directors of Spero, and because of their ability to control the business and corporate affairs of Spero, the Individual Defendants owed Spero and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Spero in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Spero and its shareholders so as to benefit all shareholders equally.

70. Each director and officer of the Company owes to Spero and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligations of fair dealing.

71. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Spero, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein.

72. To discharge their duties, the officers and directors of Spero were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

73. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good

faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Spero, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

74. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, including the dissemination of false information regarding the Company's business, prospects, and operations, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful and accurate information.

75. To discharge their duties, the officers and directors of Spero were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Spero were required to, among other things:

(a) ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Delaware, Massachusetts, and the United States, and pursuant to Spero's own Code of Business Conduct and Ethics (the "Code of

Conduct”);

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company’s assets, and to maximize the value of the Company’s stock;

(c) remain informed as to how Spero conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Spero and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Spero’s operations would comply with all applicable laws and Spero’s financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company’s shareholders would be accurate;

(f) exercise reasonable control and supervision over the public statements made by the Company’s officers and employees and any other reports or information that the Company was required by law to disseminate;

(g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate

disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

76. Each of the Individual Defendants further owed to Spero and the shareholders the duty of loyalty requiring that each favor Spero's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence or knowledge of the affairs of the Company to gain personal advantage.

77. At all times relevant hereto, the Individual Defendants were the agents of each other and of Spero and were at all times acting within the course and scope of such agency.

78. Because of their advisory, executive, managerial, and directorial positions with Spero, each of the Individual Defendants had access to adverse, non-public information about the Company.

79. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Spero.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

80. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and assisted each other in breaching their respective duties.

81. The purpose and effect of the conspiracy, common enterprise, and common course of conduct was, among other things, to: (i) facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, and violations of the Exchange Act; (ii) conceal adverse information concerning the

Company's operations, financial condition, legal compliance, future business prospects and internal controls; and (iii) artificially inflate the Company's stock price.

82. The Individual Defendants accomplished their conspiracy, common enterprise, and common course of conduct by causing the Company purposefully or recklessly to conceal material facts, fail to correct such misrepresentations, and violate applicable laws. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants who is a director of Spero was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and common course of conduct complained of herein.

83. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each of the Individual Defendants acted with actual or constructive knowledge of the primary wrongdoing, either took direct part in, or substantially assisted in the accomplishment of that wrongdoing, and was or should have been aware of his or her overall contribution to and furtherance of the wrongdoing.

84. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants, and of Spero, and was at all times acting within the course and scope of such agency.

SPERO'S CODE OF CONDUCT AND CORPORATE GOVERNANCE

Code of Business Conduct and Ethics

85. The Company's Code of Conduct starts by stating that it "sets forth legal and ethical standards of conduct for employees, officers and directors of Spero Therapeutics, Inc."

86. The Code of Conduct continues, “This Code is intended to deter wrongdoing and to promote the conduct of all Company business in accordance with high standards of integrity and in compliance with all applicable laws and regulations.”

87. Under the heading, “Compliance with Laws, Rules and Regulations,” the Code of Conduct states, “The Company requires that all employees, officers and directors comply with all laws, rules and regulations applicable to the Company wherever it does business. You are expected to use good judgment and common sense in seeking to comply with all applicable laws, rules and regulations[.]”

88. The Code of Conduct provides, as to “Conflicts of Interest,” that:

Employees, officers and directors must act in the best interests of the Company. You just refrain from engaging in any activity or having a personal interest that presents a “conflict of interest” and should seek to avoid even the appearance of a conflict of interest. A conflict of interest occurs when your personal interests interferes with the interests of the Company. A conflict of interest can arise whenever you, as an employee, officer or director, take action or have an interest that prevents you from performing your Company duties and responsibilities honestly, objectively and effectively.

89. The Code of Conduct provides, as to “Insider Trading,” that:

Employees, officers and directors who have material non-public information about the Company or other companies, including our suppliers and customers, as a result of their relationship with the Company are prohibited by law and Company policy from trading in securities of the Company or such other companies, as well as from communicating such information to others who might trade on the basis of that information. To help ensure that you do not engage in prohibited insider trading and avoid even the appearance of an improper transaction, the Company has adopted an Insider Trading Policy. You are expected to become familiar with this policy.

90. The Code of Conduct provides, as to “Confidentiality,” that:

Employees, officers and directors must maintain the confidentiality of confidential information entrusted to them by the Company or other companies, including our suppliers and customers, except when disclosure is authorized by a supervisor or legally mandated. Unauthorized disclosure of any confidential information is prohibited. Additionally, employees should take appropriate precautions to ensure that confidential or sensitive business information, whether it is proprietary to the

Company or another company, is not communicated within the Company except to employees who have a need to know such information to perform their responsibilities for the Company.

Third parties may ask you for information concerning the Company. Subject to the exceptions noted in the preceding paragraph, employees, officers and directors (other than the Company's authorized spokespersons) must not discuss internal Company matters with, or disseminate internal Company information to, anyone outside the Company, except as required in the performance of their Company duties and, if appropriate, after a confidentiality agreement is in place. This prohibition applies particularly to inquiries concerning the Company from the media, market professionals (such as securities analysts, institutional investors, investment advisers, brokers and dealers) and security holders. All responses to inquiries on behalf of the Company must be made only by the Company's authorized spokespersons. If you receive any inquiries of this nature, you must decline to comment and refer the inquirer to your supervisor or one of the Company's authorized spokespersons. The Company's policies with respect to public disclosure of internal matters are described more fully in the Company's Disclosure Policy.

91. The Code of Conduct provides, as to "Honest and Ethical Conduct and Fair Dealing," that:

Employees, officers and directors should endeavor to deal honestly, ethically and fairly with the Company's suppliers, customers, competitors and employees. Statements regarding the Company's products and services must not be untrue, misleading, deceptive or fraudulent. You must not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation or material facts or any other unfair-dealing practice.

92. The Code of Conduct provides, as to "Protection and Proper Use of Corporate Assets," that:

Employees, and officers and directors should seek to protect the Company's assets, including proprietary information. Theft, carelessness and waste have a direct impact on the Company's financial performance. Employees, officers and directors must use the Company's assets and services solely for legitimate business purpose of the Company and not for any personal benefit or the personal benefit of anyone else.

Employees, officers and directors must advance the Company's legitimate interests when the opportunity to do so arises. You must not take for yourself personal opportunities that are discovered through your position with the Company or the use of property or information of the Company.

93. The Code of Conduct provides, as to “Accuracy of Books and Records and Public Reports,” that:

Employees, officers and directors must honestly and accurately report all business transactions. You are responsible for the accuracy of your records and reports. Accurate information is essential to the Company’s ability to meet legal and regulatory obligations.

All Company books, records and accounts shall be maintained in accordance with all applicable regulations and standards and accurately reflect the true nature of the transactions they record. The financial statements of the Company shall conform to generally accepted accounting rules and the Company’s accounting policies. No undisclosed or unrecorded account or fund shall be established for any purpose. No false or misleading entries shall be made in the Company’s books or records for any reason, and no disbursement of corporate funds or other corporate property shall be made without adequate supporting documentation.

It is the policy of the Company to provide full, fair, accurate, timely and understandable disclosure in reports and other documents filed with, or submitted to, the Securities and Exchange Commission and in other public communications.

Audit Committee Charter

94. The Charter of the Audit Committee of the Board of Directors of Spero (the “Audit Committee Charter”) defines the responsibilities of the Company’s Audit Committee.

95. Per the Audit Committee Charter, the purpose of the Audit Committee is to “assist the Board’s oversight of the Company’s accounting and financial reporting processes and the audits of the Company’s financial statements.”

96. The Audit Committee Charter lists, among the Audit Committee’s responsibilities:

The Audit Committee shall discharge its responsibilities, and shall assess the information provided by the Company’s management and the Company’s registered public accounting firm (the “independent auditor”), in accordance with its business judgment. Management is responsible for the preparation, presentation, and integrity of the Company’s financial statements, for the appropriateness of the accounting principles and reporting policies that are used by the Company and for establishing and maintaining adequate internal control over financial reporting. The independent auditor is responsible for auditing the Company’s financial statements and, when required, the Company’s internal control over financial reporting and for

reviewing the Company's unaudited interim financial statements. The authority and responsibilities set forth in this Charter do not reflect or create any duty or obligation of the Audit Committee to plan or conduct any audit, to determine or certify that the Company's financial statements are complete, accurate, fairly presented, or in accordance with generally accepted accounting principles or applicable law, or to guarantee the independent auditor's reports.

* * *

Review of Other Financial Disclosures

10. Independent Auditor Review of Interim Financial Statements. The Audit Committee shall direct the independent auditor to use its best efforts to perform all reviews of interim financial information prior to disclosure by the Company of such information and to discuss promptly with the Audit Committee and the Chief Financial Officer any matters identified in connection with the auditor's review of interim financial information which are required to be discussed by applicable auditing standards. The Audit Committee shall direct management to advise the Audit Committee in the event that the Company proposes to disclose interim financial information prior to completion of the independent auditor's review of interim financial information.

11. Earnings Release and Other Financial Information. The Audit Committee shall discuss generally the type and presentation of information to be disclosed in the Company's earnings press release, including any non-GAAP financial information, as well as financial information and earnings guidance provided to analysts, rating agencies and others.

12. Quarterly Financial Statements. The Audit Committee shall discuss with the Company's management and independent auditor the Company's quarterly financial statements, including the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Other Duties

13. Controls and Procedures. The Audit Committee shall coordinate the Board's oversight of the Company's internal control over financial reporting, disclosure controls and procedures and code of conduct. The Audit Committee shall receive and review the reports of the Chief Executive Officer and the Chief Financial Officer required by Rule 13a-14 under the Exchange Act and be informed of (i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Corporation's ability to record, process, summarize and report financial information, and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Corporation's internal control over financial reporting.

* * *

15. Risk Management. The Audit Committee shall discuss the Company's policies with respect to risk assessment and risk management, including guidelines and policies to govern the process by which the Company's exposure to risk is handled.

* * *

19. Legal Regulatory and Compliance. The Audit Committee shall periodically discuss with the Chief Financial Officer (i) any legal matters that may have a material impact on the Company's financial statements, accounting policies, compliance with applicable laws and regulations and (ii) any material reports, notices or inquiries received from regulators or governmental agencies. The Audit Committee shall have direct communication with the Company's outside legal counsel, as needed.

97. In violation of the Code of Conduct, the Individual Defendants conducted little, if any, oversight of the Company's engagement in the Individual Defendants' scheme to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, and violations of the Exchange Act. Moreover, in violation of the Code of Conduct, the Individual Defendants failed to maintain the accuracy of Company records and reports, comply with laws and regulations, conduct business in an honest and ethical manner, and properly report known violations of the Code of Conduct and law.

98. Moreover, the Individual Defendants who served on the Company's Audit Committee during the Relevant Period violated the Audit Committee Charter by engaging in or permitting the Company to engage in issuing materially false and misleading statements to the investing public and facilitating and disguising the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, and violations of the Exchange Act. In addition, the Individual Defendants who served on the Company's Audit Committee during the Relevant Period violated the Audit Committee Charter by failing to

adequately oversee the integrity of the Company's financial disclosures, failing to adequately oversee the Company's compliance with legal and regulatory requirements, failing to adequately oversee the Company's risk assessments and risk management, failing to adequately discuss with management the Company's financial information prior to public distribution, and failing to adequately oversee the Company's disclosure controls and procedures.

THE INDIVIDUAL DEFENDANTS' MISCONDUCT

Background on cUTIs

99. UTIs can cause severe, and sometimes even life-threatening, health issues that require emergency medical intervention if left untreated. Around ninety percent of UTIs are classified as gram-negative pathogens. Gram-negative pathogens include Enterobacterales, with *Escherichia coli*, commonly known as *E. coli*, as the most common. Some Enterobacterales pathogens, such as expanded-spectrum β -lactamase positive (ESBL+), fluoroquinolone-nonsusceptible (FQNS), and trimethoprim-sulfamethoxazole-resistant (TMP-SMX-R), are known to resist antibiotic treatments. Around ten percent of UTIs are gram-positive. Gram-positive pathogens include Enterococci, with *Enterococcus Faecalis* as the most common.

100. UTIs are classified as cUTIs if a patient develops a UTI and the patient has a functional, metabolic, or anatomical condition that could raise the risk of treatment failure or other poor results. UTIs that manifest in men and children are frequently classified as cUTIs due to their rare occurrence and difficulty in treatment. UTIs that manifest in women can be classified as cUTIs as well, and factors that often trigger the cUTI classification in women include, but are not limited to, age, pregnancy, cancer, diabetes, bladder obstructions, and weakened immune systems. Additionally, UTIs can also be classified as cUTIs if the UTI is not affected by first-level oral antibiotic treatment.

101. Carbapenems are antibiotics that are given intravenously to patients with MDR infections that do not respond to first-level oral antibiotic treatments. Carbapenems are potent and only given to hospitalized patients. IV ertapenem is the only FDA-approved carbapenem used to fight MDR infections that do not respond to first-level oral antibiotic treatments in the United States. Since IV ertapenem is costly and requires hospitalization, the FDA approval of an orally administered treatment for patients with MDR infections that do not respond to first-level oral antibiotic treatments could prevent hospitalization, shorten hospitalization for already-hospitalized patients, and offer a much cheaper alternative medication to IV ertapenem. Recently, throughout the Relevant Period and extending to the present day, the COVID-19 pandemic has exacerbated the issue of patients wanting to avoid hospitalization, thereby making the FDA approval of an oral antibiotic treatment for cUTIs even more pressing, and lucrative for drug makers.

Background on Spero and the Advent of Tebipenem HBr

102. Spero is a Delaware corporation founded in 2013 that is based in Cambridge, Massachusetts. Spero describes itself as “a multi-asset, clinical-stage, biopharmaceutical company focused on identifying, developing and commercializing novel treatments for bacterial infections, including multi-drug resistant (‘MDR’) bacterial infections, and rare diseases.”

103. Leading into the Relevant Period, Spero had three drug candidates. Two of the early-stage drug candidates were SPR206, which was a direct, intravenous treatment for hospitalized patients with MDR gram-negative bacterial infections and the other was SPR270, which was an oral treatment for patients with non-tuberculous mycobacterial pulmonary disease. The Company’s lead product candidate was SPR994, known as Tebipenem HBr, which is an oral carbapenem used to treat cUTIs and acute pyelonephritis. Spero sought approval from the FDA

for Tebipenem HBr for use in pill form as an anti-bacterial medication to offer an alternative to the onerous, already-FDA approved ertapenem, which is administered intravenously.

104. Tebipenem is a carbapenem antimicrobial. Tebipenem pivoxil is the orally bioavailable prodrug of tebipenem that prevents the stomach acid from breaking apart the active drug. Years ago, Tebipenem pivoxil was developed by Japanese drug maker Meiji Seika Pharma Co. Ltd. (“Meiji”). For this reason, since 2009, Tebipenem pivoxil has been marketed in Japan under the name Orapenem. In Japan, Orapenem is used in granule form to treat rudimentary pediatric infections. Subsequently, tebipenem pivoxil was licensed to Spero.

105. Tebipenem HBr, which underwent testing in the Phase 3 ADAPT-PO Trial, is tebipenem pivoxil hydrobromide, which is the orally bioavailable carbapenem prodrug (tebipenem pivoxil) stuffed into a pill capsule with HBr salt. Spero designed Tebipenem HBr to permit high dosage in treatments and make a room-temperature-stable drug candidate. Additionally, with Tebipenem HBr, Spero attempted to introduce to the United States market the first broad spectrum oral carbapenem antibiotic for treating patients with MDR gram-negative infections, including cUTIs and acute pyelonephritis (“AP”).

106. Multiple analysts viewed Spero’s attempt to bring Tebipenem HBr through FDA approval as low risk since Japan had already demonstrated the safety, tolerability, and efficacy of tebipenem pivoxil through actual, real-world use of the drug. Moreover, Meiji had already conducted two Phase 2 clinical trials which demonstrated tebipenem was widely successful in treating cUTIs.

107. Given these expectations and the fact that Spero had no other drug products on the market before and during the Relevant Period, the Company was highly dependent on Tebipenem HBr obtaining FDA approval, and in turn, bringing Tebipenem HBr to market in the United States.

Spero Begins Seeking FDA Approval of Tebipenem HBr; the Market Carefully Follows

108. On October 20, 2017, Spero announced the launch of a Phase 1 trial focusing on the safety and tolerability of Tebipenem HBr. In the announcement, the Company touted a “rapid development approach” for the drug candidate, stating that if Phase 1 produced positive results, Spero would quickly move to a single, Phase 3 clinical trial. In the same announcement, Spero also reported that the FDA deemed Tebipenem HBr a QIDP, or Qualified Infectious Disease Product, for cUTIs. QIDP status gave Spero strong incentives such as priority FDA review and possible market exclusivity were Spero to bring Tebipenem HBr to market.

109. Just three days after announcing the launch of the Phase 1 study, Spero announced its IPO for trading on the NASDAQ GS, which concluded on November 6, 2017. The IPO injected approximately \$83.6 million into the Company. Throughout the IPO, Spero stressed the Company’s “rapid development approach” for Tebipenem HBr, especially the prospect of launching a Phase 3 clinical trial.

110. After the IPO, analysts and investors were bullish about Spero and its ability to successfully navigate and execute the Phase 3 ADAPT-PO Trial. For instance, Oppenheimer, in a November 27, 2017 report, gave Spero an “Outperform” rating, writing that Tebipenem HBr is a “unique oral carbapenem option that could accelerate hospital discharge, reduce total cost of treatment and decrease reinfection rates” and “[w]ith a pivotal Ph3 cUTI study expected to complete in 2020 and an expedited regulatory review, we expect SPR994 to receive FDA approval for complicated urinary tract infections (cUTI) and launch in 2021.” Similarly, Cowen forecasted an “excellent chance of success for the planned Ph3 of lead drug SPR994 in cUTI” and viewed the “safety dataset as a differentiating factor for [SPR994], as many antibiotic candidates fail in the clinic due to human safety.”

111. On February 4, 2019, the FDA accepted Spero's IND application for Tebipenem HBr, which allowed Spero to deliver the drug candidate across state lines to clinical investigators for evaluation. In turn, Spero began patient enrollment in the United States for its "pivotal" global Phase 3 ADAPT-PO Trial.

112. A little over a month later, on March 29, 2019, Spero announced that the FDA had granted Tebipenem HBr Fast Track Designation, which spurs faster development and quickens the FDA's evaluation of drug candidates meant for use in serious or life-threatening conditions that present the possible capability of meeting unmet medical needs. To facilitate successful Fast Track Designation, the FDA interacts more often with drug candidate companies than it normally would, and also offers rolling review of NDAs. In Spero's case, the Company was given the opportunity to discuss the ADAPT-PO Trial with the FDA more often than normal and could do so in more detail.

113. By May 2020, Spero completed enrollment in the ADAPT-PO Trial, compiling a population of 1,372 patients. In an earnings press release issued on August 6, 2020, Spero reported that the Company expected to report top-line data from the ADAPT-PO Trial in the third quarter of 2020.

114. However, unknown to investors and the public, Spero's NDA was rife with deficiencies that would prevent the FDA from approving Tebipenem HBr, especially with regard to the ADAPT-PO Trial's patient population. Specifically, the FDA reanalyzed data gathered from the ADAPT-PO Trial after taking patients who had gram-positive bacteria out of the study. The FDA removed these patients because gram-positive bacteria, such as staphylococcus, have different cellular structures than gram-negative bacteria, such as E. coli. *IV ertapenem is also not FDA-approved to treat gram-positive bacteria, so it would be ineffectual and unhelpful to*

include gram-positive bacteria in the data set. Moreover, since gram-negative bacteria commonly cause cUTIs and gram-positive bacteria are thought to be resistant to tebipenem, it would be inappropriate to include the gram-positive patients in the trial. For this reason, the ADAPT-PO Trial's patient population was too small, and crucially, once the gram-positive patients were removed, Tebipenem HBr's efficacy compared to IV ertapenem did not meet the required -12.5% noninferiority margin. Despite the Individual Defendants' knowledge of these issues, they chose to shower themselves with high compensation and bonuses and engage in insider trading while Spero's stock price traded at artificially inflated prices due to the false and misleading statements made by the Individual Defendants.

115. As mentioned above, plaintiffs' counsel in the Securities Class Action interviewed six former employees of Spero, whose statements are contained in the Securities Class Action's "First Amended Class Action Complaint" (the "Class Action Complaint"). The statements attributed to the various former employees ("CWs") below come from their statements in the Class Action Complaint. The CWs corroborate the many problems facing the Company's internal controls, the FDA's Fast Track approval program, and the NDA, among other things.

116. One such former employee, identified as CW1 in the Class Action Complaint, worked at Spero as a Director of Clinical Data Management from February 2019 to February 2022. CW1 stated that the FDA's Fast Track program operates at a much faster rate than the normal approval process. CW1 stated that, "My experience with Fast Track, the FDA, they hold your hand through the whole (process). They'll tell you, 'You're missing this,' and 'You need to have that.' Whatever needs to be done. Because they are fast-tracking it."

117. CW2, an Associate Director in the Spero Regulatory Affairs Department, was responsible for processing and responding to the FDA's many inquiries about the Tebipenem HBr

NDA. CW2 stated that when the FDA sent Spero questions, CW2, along with other relevant employees, would determine what data was needed to properly respond to the inquiry. According to CW2, by December 2021, the FDA sought information about clinical, non-clinical, and CMC (Chemistry, Manufacturing, and Control) problems: “Starting in December 2021, we got a lot of comments back from the FDA – requests for additional information on various topics: clinical, non-clinical, CMC [Chemistry, Manufacturing, and Control]. That continued through December. January and February – that was the peak. We got questions from [the FDA] just about every week, even a couple times a week.”

118. CW2 further stated, as to the volume of inquiries, “We just got so many questions. But a lot of them were clinical.” CW2 did maintain that Spero timely fielded the questions before deadlines, but stated that the number of questions was unusual, especially in light of CW2’s lengthy, twenty-year career experience in dealing with NDAs and the FDA: “I felt it was weird that the FDA was asking all of those questions. In my experience, I didn’t see that too much – as much as I did with this NDA and Spero.” Because of the unusual number of inquiries, CW2 wondered if Spero’s NDA was weak.

119. Suspiciously, approximately one month before the truth about the NDA’s deficiencies was revealed by Spero in a March 31, 2022 press release, VP of Regulatory Affairs Jennifer Liscouski, acting on orders from the “leadership team,” instructed CW2 to make all files housed in Spero’s computer system regarding the Tebipenem HBr NDA confidential, so that access to the files would be prohibited except for a select group of employees including Defendant Mahadevia, one C-suite executive, three individuals in regulatory affairs, including CW2, and two individuals in CMC.

120. In March 2022, a company-wide conference call was held to inform Spero employees that the FDA had identified deficiencies in the Tebipenem HBr NDA. CW3, who worked as Lead Medical Science Liaison Director from May 2021 until they were abruptly laid off in May 2022, stated that the announcement took CW3, and others, totally by surprise. CW3 noted that the Individual Defendants did not want to provide details on what the identified deficiencies were. A Medical Science Liaison, identified as CW4, corroborated CW3's account of the March 2022 conference call, adding that Defendants Mahadevia and Shukla attended the call as well. CW4 stated that the Individual Defendants told the employees that Spero had received a letter from the FDA about deficiencies in the NDA, but they would not provide the details. In particular, CW4 stated that "They knew details of the deficiencies, but they were not going to share it. They didn't let you know if it was regarding the research, the manufacturing, nothing. There was no indication of what it could have been."

121. To this end, CW4 maintains that Company leadership was aware that Spero employees wanted to know the details but claimed that if they provided the details of the deficiencies, the FDA would view their disclosure of this information as "bad faith" and possibly slow the approval process even further. Indeed, instead of telling the truth to Spero's own employees, CW4 stated that Company leadership decided to falsely characterize the deficiency letter as a positive development, stating that "They kept saying, 'We have a great team, we caught it early, it's early in the timing of the PDUFA, we feel comfortable we can work it out with FDA.'"

122. Unfortunately for Spero's employees, they believed in the Individual Defendants' characterization of the situation. CW6, who worked as a Medical Science Liaison from January 2021 until they were fired in May 2022, noted that Company leadership "kept it very close to the vest" during the March 2022 conference call, but trusted Company leadership. Company

leadership made it appear that Spero could remedy the deficiencies at the Late Cycle Meeting with the FDA in the coming weeks. For these reasons, CW6 was “stunned” at how quickly Spero fired its employees and reversed course in May 2022. CW6 further noted that, due to the sheer size of the workforce reduction, Company leadership must have planned it far in advance, stating “Those plans had to be well under way to just pull the plug on all of us. It takes time to law that (action) out and run the numbers.”

123. CW3 and CW4 only learned of the truth that the FDA had removed the gram-positive patients from the ADAPT-PO Trial, causing Tebipenem HBr to miss its required -12.5% noninferiority margin, *after* they were terminated in May 2022.

124. Throughout the Relevant Period, the investing public was under a false impression of the Company’s business, operations, financial success, and growth. Specifically, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements to the investing public that failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval; (3) Spero faced an unusually high amount of questions and inquiries from the FDA before and after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company’s workforce and a shift in the Company’s focus; (6) due to the foregoing, Spero’s reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed

to maintain adequate internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

False and Misleading Statements

September 8, 2020 8-K

125. On September 8, 2020, Spero filed a Form 8-K with the SEC (the "September 8, 2020 8-K") that announced top-line results for the ADAPT-PO Trial focusing on Tebipenem HBr.

The September 8, 2020 8-K stated, in relevant part:

The pivotal Phase 3 clinical trial of oral tebipenem HBr met the primary endpoint, demonstrating statistical non-inferiority versus IV ertapenem.¹ The primary endpoint of the trial was defined as the overall response rate (combined clinical cure plus microbiological eradication) at the test-of-cure ("TOC") visit in the microbiological-intent-to-treat population ("micro-ITT"). Favorable overall ***response rates at TOC were 58.8% versus 61.6% for tebipenem HBr and ertapenem, respectively (treatment difference, -3.3%; 95% confidence interval [CI]: -9.7, 3.2; -12.5% NI margin).*** Clinical cure rates at TOC were high, at greater than 93% in both treatment groups, and overall response rates were consistent across key subgroups of interest.

The primary endpoint was the overall response, defined as the combination of clinical cure and microbiological eradication of the causative pathogen(s), at the TOC visit (Day 19, plus or minus 2 days) and was assessed in the micro-ITT population. The primary analysis and assessment of non-inferiority was evaluated using a pre-specified -12.5% non-inferiority ("NI") margin. This NI margin was a modification of the original NI margin of -10% that was discussed with the U.S. Food and Drug Administration ("FDA") because of concern that the COVID-19 pandemic could have an adverse effect on the trial. As a result, the NI margin was modified prior to database lock from the original NI margin. However, as noted by the lower bound of the 95% confidence interval (- 9.7), the trial also achieved success according to the original -10% NI margin. The Company plans to present emerging data from tebipenem HBr program, including the ADAPT-PO clinical trial results, in detail at future scientific meetings and in publications. ***The Company intends to initiate a rolling New Drug Application ("NDA") submission and anticipates completing the NDA submission to the FDA for tebipenem HBr in the second quarter of 2021.***

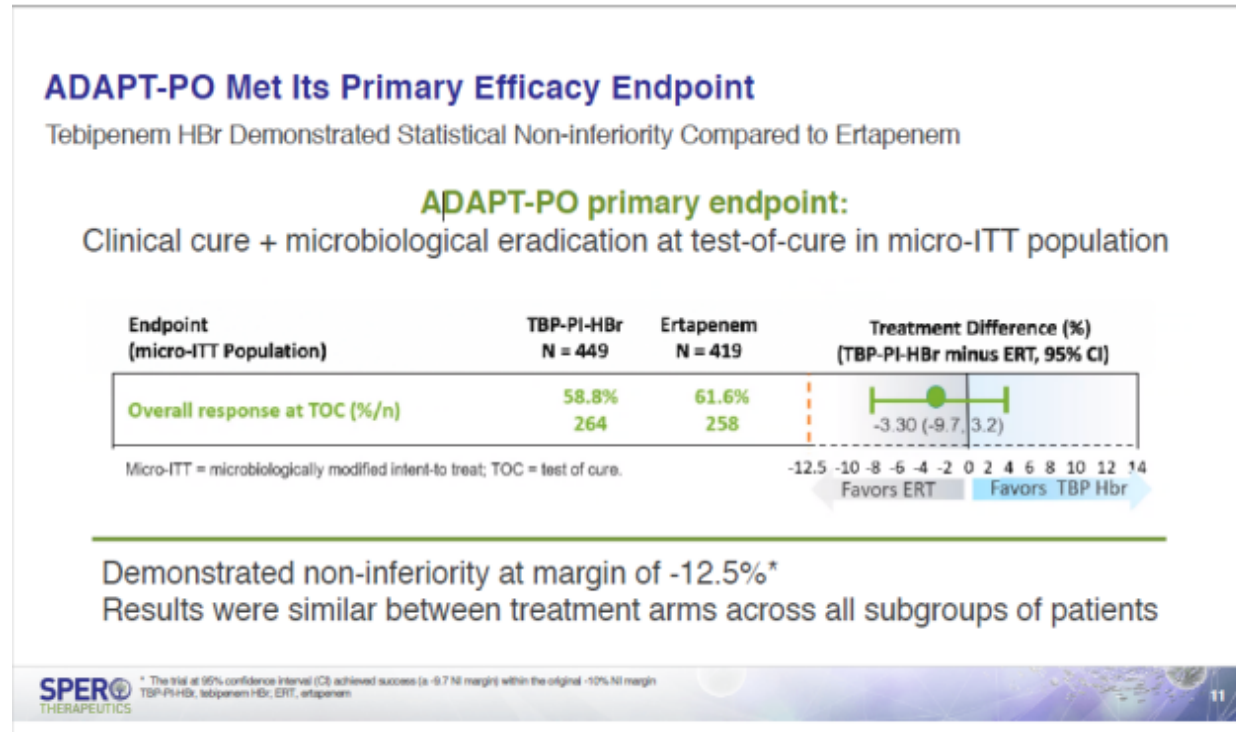
¹ All emphasis is added unless otherwise indicated.

126. The September 8, 2020 8-K also contained attachments, including Exhibit 99.1, which featured an investor presentation entitled, “Spero Therapeutics ADAPT-PO Phase 3 Topline Data Conference Call.” The slides in the presentation boasted that the ADAPT-PO Trial was a “landmark” study that produced “robust” results and further claimed that the data gleaned from the ADAPT-PO Trial supported an NDA submission for Tebipenem HBr in the second quarter of 2021. Among other things, the slides stated that “ADAPT-PO Met Primary Endpoint” and “Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin).” The slides also stated that “tebipenem HBr, as the first oral carbapenem, could allow appropriate patients the opportunity to receive treatment in the community setting.” The slides emphasized the importance of meeting the 12.5% non-inferiority margin, stating that “ADAPT-PO Met Its Primary Efficacy Endpoint: ***Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem...at margin of -12.5%***” and that the “Results were similar between treatment arms across all subgroups of patients.”

127. The slides also stated that “ADAPT-PO Key Secondary Endpoints Support Robust Patient Outcomes: Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms.” The slides also characterized the ADAPT-PO Trial as the “One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions” and further stated that “Positive ADAPT-PO Trial Results Support an NDA submission in 2Q21.”

128. The slides also referenced Spero’s funding which was supporting the NDA submission, stating that the Company was “Funded into the first quarter of 2022, through the NDA submission and the approval process for tebipenem HBr,” “BARDA/DTRA non-dilutive funding award for tebipenem HBr up to \$56.7M” with “additional awards and alliances provid[ing] funding

for the pipeline,” and that “Tebipenem HBr Well Positioned to Recognize Significant Market Opportunity.” The following slides were included in the presentation, and were repeatedly referenced by the Individual Defendants throughout the Relevant Period:

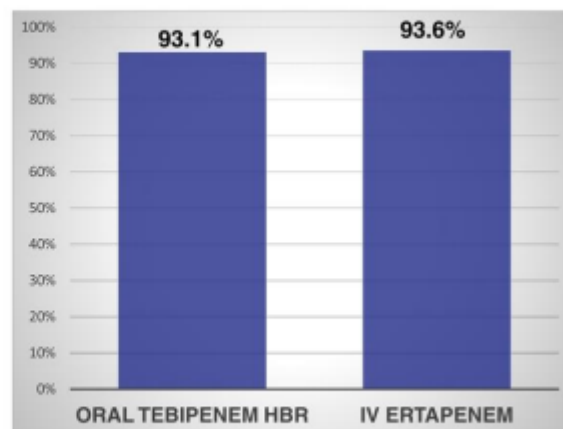


ADAPT-PO Key Secondary Endpoints Support Robust Patient Outcomes

Clinical cure rates at test-of cure for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms

Median duration of therapy was similar for both treatment groups

Comparable Clinical Cure Rates at TOC



129. On September 8, 2020, and attached as Exhibit 99.2 to the September 8, 2020 8-K, Spero issued a press release which substantially repeated the same statements made in the September 8, 2020 8-K. The press release stated that “[r]esults demonstrate that tebipenem HBr was non-inferior compared to ertapenem with respect to the trial’s primary endpoint, overall response (combined clinical cure plus microbiologic eradication) at the test-of-cure (TOC) visit in the microbiological-intent-to-treat (micro-ITT) population.”

130. The press release also stated that “The favorable overall response rates were 58.8% (264/449) versus 61.6% (258/419) for tebipenem HBr and ertapenem, respectively (treatment difference, -3.3%; 95% confidence interval [CI]: -9.7, 3.2; -12.5% NI margin).” The press release further stated that “Clinical cure rates at TOC were high (>93%) in both treatment groups,” “Overall response rates were consistent across key subgroups of interest, including age, baseline diagnosis, and presence of bacteremia,” and “[p]er pathogen microbiological response was balanced across treatment groups for most prevalent uropathogens.”

131. The press release also discussed the plans for an NDA submission, declaring that “Spero intends to initiate a rolling NDA submission and anticipates completing the NDA submission to the FDA for tebipenem HBr in the second quarter of 2021.” In the press release, Defendant Mahadevia called the ADAPT-PO Trial a “landmark” study and also stated the results were “positive” and “demonstrate the value of tebipenem HBr.”

September 14, 2020 Prospectus Supplement

132. On September 14, 2020, Spero filed a Prospectus Supplement on Form 424B5 with the SEC (the “September 14, 2020 Prospectus Supplement”), supplementing the Company’s already-filed December 3, 2018 Prospectus. The September 14, 2020 Prospectus Supplement characterized Tebipenem HBr as the Company’s “most advanced product candidate” and stated

there were “positive topline results” for the “Phase 3 ADAPT-PO clinical trial of oral tebipenem HBr in complicated urinary track infection and acute pyelonephritis.”

133. The September 14, 2020 Prospectus Supplement further stated that “[t]he pivotal Phase 3 clinical trial of oral tebipenem HBr met the primary endpoint, demonstrating statistical non-inferiority versus IV ertapenem.” Because of this, the September 14, 2020 Prospectus Supplement stated that the Company “intend[ed] to initiate a rolling New Drug Application (NDA) submission and anticipate[d] completing the NDA submission to the FDA for tebipenem HBr in the second quarter of 2021.”

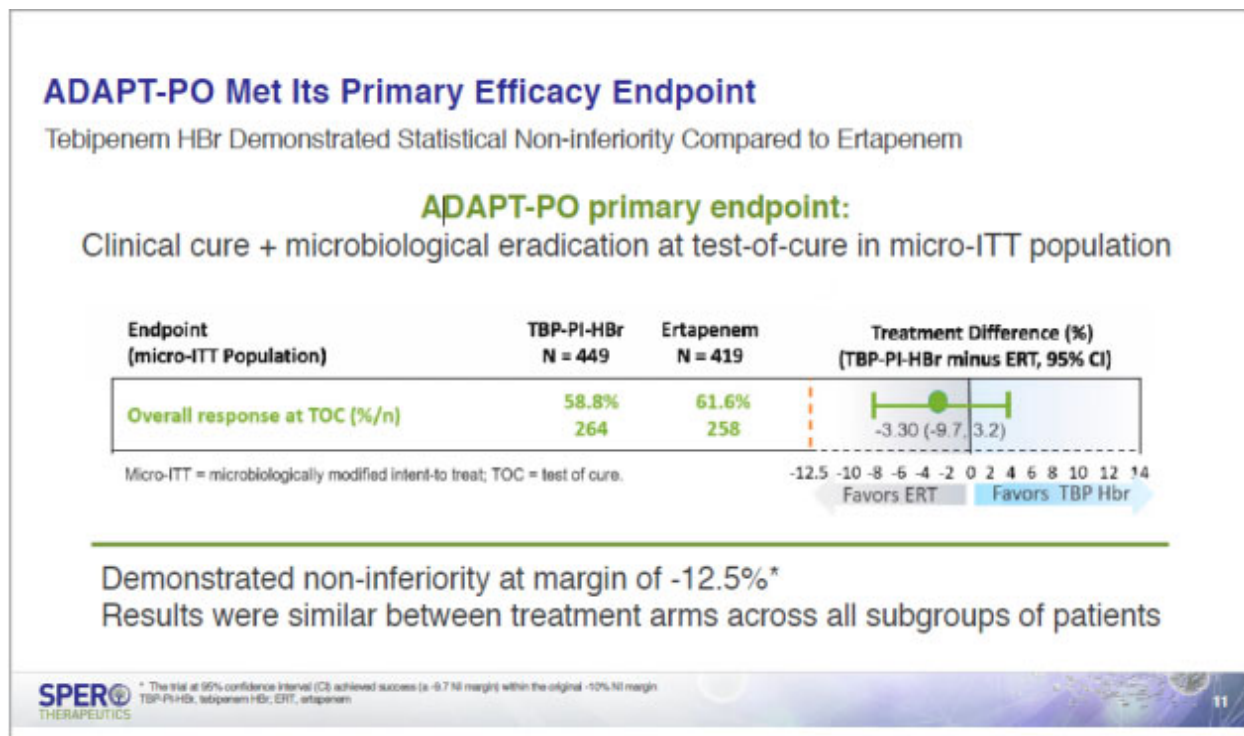
134. On September 16, 2020, Spero filed a Form 8-K with the SEC (the “September 16, 2020 8-K”), which featured an attachment to Exhibit 99.1. Exhibit 99.1 contained a series of slides used for investor presentations which were posted on the Company’s website and were otherwise disseminated in both hardcopy and electronic format.

135. The slides stated that the ADAPT-PO Trial was a “landmark” study, its results were “robust,” that “ADAPT-PO Met Primary Endpoint,” and “Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin).” The slides also emphasized Tebipenem HBr’s capabilities, stating that “Tebipenem HBr, as the first oral carbapenem, could allow appropriate patients the opportunity to receive treatment in the community setting.”

136. The slides further stated that “ADAPT-PO Met Its Primary Efficacy Endpoint: Tebipenem HBr Demonstrated Statistical Non- inferiority Compared to Ertapenem...at margin of -12.5%” based upon analyses of the micro-ITT population and that “Results were similar between treatment arms across all subgroups of patients.” The slides also stated that “ADAPT-PO Key

Secondary Endpoints Support Robust Patient Outcomes: Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms.”

137. The slides characterized the ADAPT-PO Trial as “One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions” and again touted that “Positive ADAPT- PO Trial Results Support an NDA submission in 2Q21.” The slides further discussed Spero’s funding for the NDA, stating that the Company was “Funded into the first quarter of 2022, through the NDA submission and the approval process for tebipenem HBr,” “BARDA/DTRA non-dilutive funding award for tebipenem HBr up to \$56.7M” with “additional awards and alliances provid[ing] funding for the pipeline,” and that “Tebipenem HBr [Was] Well Positioned to Recognize Significant Market Opportunity.” The following slides were included in the presentation, and were repeatedly referenced by the Individual Defendants throughout the Relevant Period:

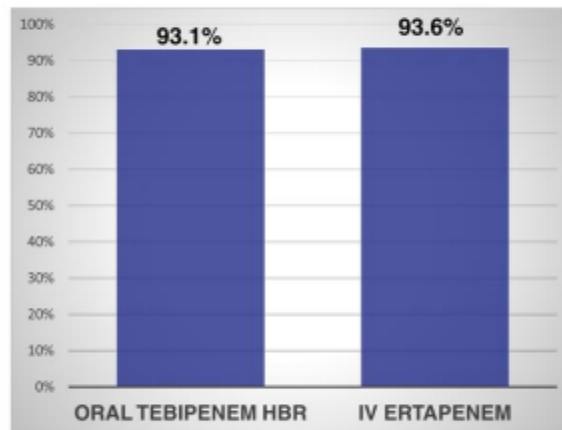


ADAPT-PO Key Secondary Endpoints Support Robust Patient Outcomes

Clinical cure rates at test-of cure for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms

Median duration of therapy was similar for both treatment groups

Comparable Clinical Cure Rates at TOC



SPERO
THERAPEUTICS

Micro-ITT = Microbiological intent to treat

8

September 17, 2020 Cantor Virtual Global Healthcare Conference

138. On September 17, 2020, Defendant Mahadevia presented on behalf of Spero during the Cantor Virtual Global Healthcare Conference which was held between September 15-17, 2020. During the prepared portion of Defendant Mahadevia's presentation, he stated that "oral tebipenem is comparable in its effectiveness for cUTI patients to IV ertapenem meeting the minus 12.5 percent non-inferiority margin set up by the FDA." He told investors and analysts that the Company was on pace to submit its NDA for Tebipenem HBr, stating: "[i]ts NDA submission is planned for the second quarter of 2021," and "we'll plan for a pre-NDA meeting with the FDA, as well as completing the ancillary Phase 1 trials that are required as part of that package – all of that is on track and it's consistent with our guidance of completing the filing in the second quarter of next year."

139. Defendant Mahadevia also connected the Company's ability to raise funds with the success of the ADAPT-PO Trial, stating that "On the heels of positive data, we were fortunate to raise a follow-on financing and, you know, because of that and including our existing cash, we

have a strong cash position – 71 million as of the last quarterly filing not including follow-on financing proceeds of \$80 million.”

September 23, 2020 Oppenheimer Fall Healthcare Life Sciences & MedTech Summit

140. Less than a week later, on September 23, 2020, Defendant Mahadevia presented on behalf of Spero during Oppenheimer’s Fall Healthcare Life Sciences & MedTech Summit which was held between September 21-23, 2020. During the prepared portion of Defendant Mahadevia’s presentation, he stated that “ADAPT-PO met its primary endpoint...[e]ssentially demonstrating that an all-oral regimen for this seriously ill patient population can do the job of an IV,” “the overall response rate of the cUTI population was comparable to IV ertapenem response rate within the non-inferiority margin set out by the FDA,” and “*[i]t is no small feat to have gotten an oral to do the job of an IV.*”

141. He stressed the high testing standards of the FDA, stating that “what we were looking for was 17 to 21 days after the first dose we had these patients back, we measured both how they felt based on a FDA mandated questionnaire, as well as measured the microbial burden in their urine [as the] FDA requires.” He further stated that “[T]he treatment difference between tebipenem and ertapenem was 3.3%” and “what the FDA is looking for is the lower bound of that 95% confidence interval is greater than -12.5% and as you can see here, we did clear that...very high bar...given this was an all-oral regimen in a very ill population.”

142. Defendant Mahadevia also highlighted the ADAPT-PO Trial’s data, referencing the patient population but not mentioning the difference between gram-positive and gram-negative bacteria, stating, “[T]he study was representative of the patients that we aimed to treat” and “the representative diagnoses of both lower UTI as well as acute pyelonephritis...represents a very tough test for tebipenem – No. 1, given the high proportion of lower UTI patients which tend to

respond less well to therapy and No. 2, the 19 percent of patients that that met modified service criteria which means that they were quite ill.” He further explained, “So, this was a sicker patient population with a high proportion of resistant pathogens and our all oral medication was able to do the job.”

143. He also told investors and analysts that the NDA for Tebipenem HBr was on track, stating, “[W]e’re working hard to get our NDA submission in as planned by the second quarter of 2021” and “[w]e have pre-NDA meetings coming up as part of that cadence, and we are rapidly working to complete any ancillary Phase 1 trials that would support the NDA.”

144. During the Q and A portion of the presentation, Defendant Mahadevia replied to an analyst’s question regarding Tebipenem HBr, stating the following:

Yeah, so more broadly I would say that, you know, our first focus is ensuring that tebipenem gets approved for complicated UTI and we’re working hard filing that NDA. ***I would note that the notion that in cUTI patients we’re able to show that oral tebipenem has the same effectiveness as IV ertapenem certainly builds a wide range of possibilities.*** Ertapenem is not just used in cUTI it’s also used for patients with lung infections, intraabdominal infections, ***and a variety of other Gram-negative infections.*** And so there certainly is an opportunity to think about tebipenem being applicable where ertapenem is or where other oral antibiotics have failed.

September 24, 2020 Press Release

145. On September 24, 2020, Spero issued a press release announcing that the Company would hold an analyst and investor call approximately one week later, on September 30, 2020. The press release stated that the call would concern Tebipenem HBr and would feature Key Opinion Leader (“KOL”) Keith Kaye, MD, MPH, who would present and discuss the e ADAPT-PO Trial top-line data along with Company management.

146. The press release also stated that the “ADAPT-PO trial met its primary endpoint of demonstrating that oral tebipenem HBr is statistically non- inferior to intravenous ertapenem.”

September 30, 2020 Conference Call

147. On September 30, 2020, Spero held the aforementioned conference call with investors and analysts concerning Tebipenem HBr with Keith Kaye MD, MPH. During the call, Defendants stated that “tebipenem HBr could fulfill an important niche in cUTI,” “Spero continues to estimate it will begin a rolling submission of the NDA in 1Q21, with a final submission planned 2Q21 based on the positive Phase 3 data,” and “Spero is currently doing market research to prepare for the commercial launch of tebipenem HBr in the US.”

148. The statements referenced above in ¶¶ 125-147 were materially false and misleading, and failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants willfully or recklessly made false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval; (3) Spero faced an unusually high amount of questions and inquiries from the FDA before and after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company’s workforce and a shift in the Company’s focus; (6) due to the foregoing, Spero’s reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed to maintain adequate internal controls. As a result of the foregoing, the Company’s public statements were materially false and misleading at all relevant times.

September 30, 2020 Proxy Statement

149. On September 30, 2020, the Company filed a proxy statement on Schedule 14A with the SEC (the “2020 Proxy Statement”). Defendants Mahadevia, Deshpande, Jackson, Pottage, Smith, Thomas, Formela, and Vink solicited the 2020 Proxy Statement filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.

150. The 2020 Proxy Statement called for Company shareholders to vote to, *inter alia*: (1) elect Defendants Mahadevia and Deshpande to the Board; and (2) ratify the appointment of PricewaterhouseCoopers LLP as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2020.

151. With respect to the Company’s Code of Conduct, the 2020 Proxy Statement stated:

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, including our chief executive officer and chief financial and accounting officers. [...] Disclosure regarding any amendments to, or waivers from, provisions of the Code of Business Conduct and Ethics that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K[.]

152. Regarding the Board’s “Role in Risk Oversight,” the 2020 Proxy Statement stated:

Our Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board of Directors performs this oversight role by using several different levels of review. In connection with its reviews of the operations and corporate functions of our Company, our Board of Directors addresses the primary risks associated with those operations and corporate functions. In addition, our Board of Directors reviews the risks associated with the Company’s business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our board committees also oversees the management of the Company’s risk that falls within the committee’s areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Executive Officer reports to the Audit Committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its risk management role, our Audit Committee meets privately with representatives from our independent registered public accounting firm and our Chief Executive Officer. The Audit Committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and

periodic updates to such risks, and reports to our Board of Directors regarding these activities.

153. Defendants Mahadevia, Deshpande, Jackson, Pottage, Smith, Thomas, Formela, and Vink caused the 2020 Proxy Statement to be false and misleading by failing to disclose that: (1) though the Company claimed its directors and officers adhere to the Code of Conduct and that it would disclose waivers of the policy, the Individual Defendants violated the Code of Conduct either without waivers or without such waivers being disclosed; and (2) the Board and its committees were not properly exercising their risk oversight functions, including their review of the risk exposures described, as evidenced by the occurrence of the wrongdoing alleged herein, which involved members of the Board.

154. In addition, the 2020 Proxy Statement was materially false and misleading, and failed to disclose material facts necessary to make the statements made not false and misleading, because the 2020 Proxy Statement failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval; (3) Spero faced an unusually high amount of questions and inquiries from the FDA before and after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company's workforce and a shift in the Company's focus; (6) due to the foregoing, Spero's reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed to maintain adequate internal controls.

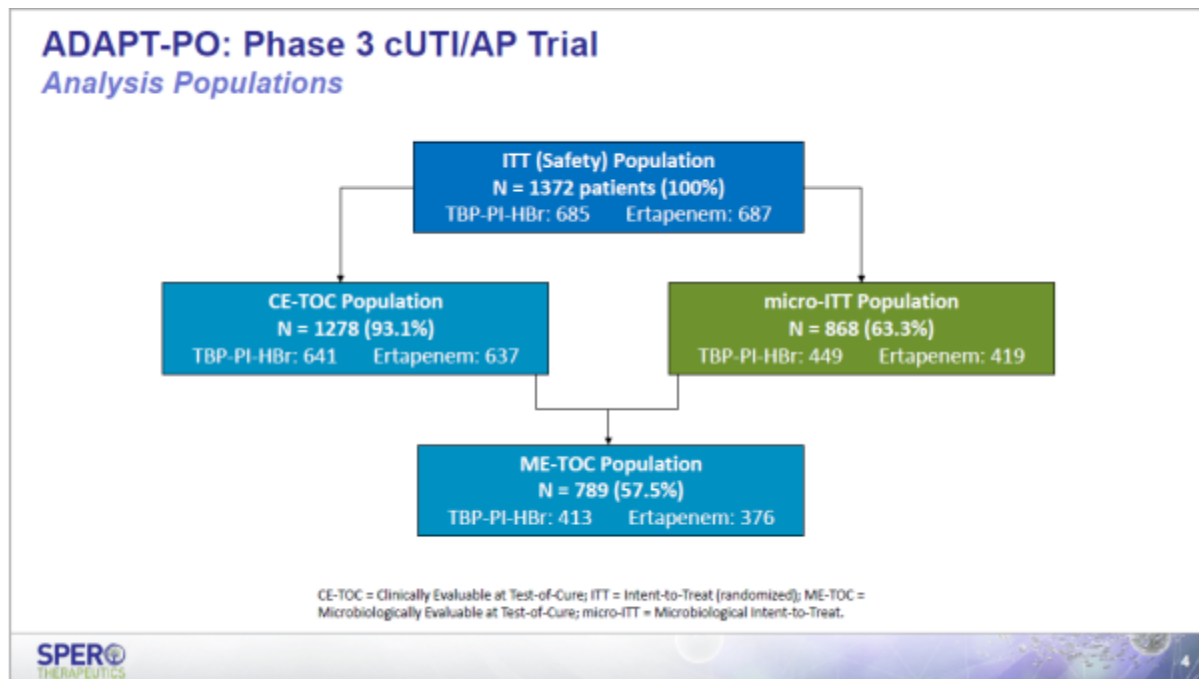
155. As a result of Defendants Mahadevia, Deshpande, Jackson, Pottage, Smith, Thomas, Formela, and Vink causing the 2020 Proxy Statement to be false and misleading, Company shareholders voted, *inter alia*, to: (1) re-elect Defendants Mahadevia and Deshpande to the Board, allowing them to continue breaching their fiduciary duties to the Company; and (2) ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2020.

October 16, 2020 Press Release

156. On October 16, 2020, Spero issued a press release that provided slide presentations intended for use at the upcoming Infectious Disease Society of America ("IDSA") IDWeek 2020 meeting to be held October 21-25, 2020. The press release emphasized "positive" top-line data from the ADAPT-PO Trial "demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous (IV) ertapenem in the treatment of patients with cUTI and patients with AP." The press release also provided a hyperlink to Spero's website that contained the slides to be used during the IDSA ID Week 2020 presentation (the "2020 IDSA ID Week Slides") and multiple presentation posters to be used during the IDSA ID Week 2020 presentation (the "2020 IDSA ID Week Posters").

157. The 2020 IDSA ID Week Slides were titled, "Oral Tebipenem is Non-Inferior to IV Ertapenem in Complicated Urinary Tract Infection (cUTI) and Acute Pyelonephritis (AP): Results From the Pivotal ADAPT-PO Study." The slides showed percentages of patients in micro-ITT divided by gram-negative bacteria and gram-positive bacteria. The slides also showed per-pathogen microbiological eradication at test-of-cure for Enterobacterales (the gram-negative pathogens), which was 63.0% in Tebipenem HBr and 65.9% in IV ertapenem.

158. The 2020 IDSA ID Week Slides stated that based upon data from the micro-ITT population, “ADAPT-PO Met the Primary Efficacy Endpoint” and that “Oral TBP-PI-HBr was non-inferior to IV ertapenem in overall response at TOC.” The 2020 IDSA ID Week Slides further referenced the successes of the ADAPT-PO Trial by stating that “Oral TBP-PI-HBr (600mg PO q8h) was non-inferior to ertapenem (1g IV q24h) in the treatment of hospitalized adult patients with cUTI/AP,” “ADAPT-PO achieved all primary and secondary objectives,” and “These effects were seen consistently across patient subsets.” The 2020 IDSA ID Week Slides also declared that the Tebipenem HBr NDA was on schedule for submission, stating, “Spero expects that data from this single pivotal trial will support submission of an NDA.” The 2020 IDSA ID Week Slides including the following slides, in relevant part:



ADAPT-PO: Phase 3 cUTI/AP Trial*Uropathogens Isolated from Urine and/or Blood at Baseline (micro-ITT)*

Baseline Pathogen*	TBP-PI-HBr (N=449)	Ertapenem (N=419)	Total (N=868)
Enterobacterales	397 (88.4%)	386 (92.1%)	783 (90.2%)
<i>Escherichia coli</i>	287 (63.9%)	270 (64.4%)	557 (64.2%)
<i>Klebsiella pneumoniae</i>	53 (11.8%)	71 (16.9%)	124 (14.3%)
<i>Proteus mirabilis</i>	35 (7.8%)	23 (5.5%)	58 (6.7%)
<i>Enterobacter cloacae</i>	11 (2.4%)	8 (1.9%)	19 (2.2%)
<i>Citrobacter freundii</i>	4 (0.9%)	3 (0.7%)	7 (0.8%)
<i>Citrobacter koseri</i>	3 (0.7%)	4 (1.0%)	7 (0.8%)
<i>Klebsiella oxytoca</i>	4 (0.9%)	3 (0.7%)	7 (0.8%)
<i>Providencia rettgeri</i>	4 (0.9%)	3 (0.7%)	7 (0.8%)
<i>Klebsiella varicola</i>	2 (0.4%)	4 (1.0%)	6 (0.7%)
<i>Serratia marcescens</i>	4 (0.9%)	2 (0.5%)	6 (0.7%)
<i>Morganella morganii</i>	4 (0.9%)	1 (0.2%)	5 (0.6%)
Gram-positive cocci	76 (16.9%)	51 (12.2%)	127 (14.6%)
<i>Enterococcus faecalis</i>	58 (12.9%)	36 (8.6%)	94 (10.8%)
<i>Staphylococcus aureus</i>	5 (1.1%)	8 (1.9%)	13 (1.5%)
<i>S. saprophyticus</i>	4 (0.9%)	6 (1.4%)	10 (1.2%)
<i>Enterococcus faecium</i>	5 (1.1%)	2 (0.5%)	7 (0.8%)

*Only pathogens representing ≥ 5 isolates across both treatment groups are presented.

- 90% patients in micro-ITT were infected with Enterobacterales
- Infections caused by resistant Enterobacterales strains were common

Enterobacterales Resistance phenotype ¹	TBP-PI-HBr	Ertapenem
ESBL+	26.5%	22.0%
FQ-non-susceptible	40.2%	37.8%
TMP-SMX-resistant	42.4%	43.5%

¹ Per CLSI screening criteria: ESBL+ = ceftazidime MIC ≥ 2 µg/mL; fluoroquinolone (FQ)-non-susceptible = levofloxacin MIC ≥ 1 µg/mL; trimethoprim-sulfamethoxazole (TMP/SMX)-resistant = TMP-SMX MIC ≥ 4/76 µg/mL.

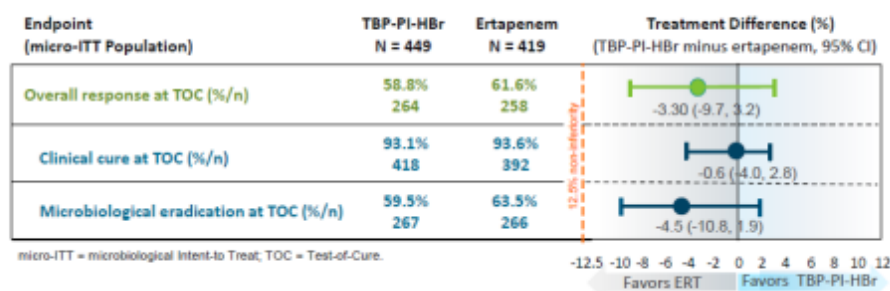
**ADAPT-PO: Phase 3 cUTI/AP Trial***Per-Pathogen Microbiological Eradication at TOC (micro-ITT)*

Baseline Pathogen	TBP-PI-HBr N=449 % (n/N1)	Ertapenem N=419 % (n/N1)
Enterobacterales*	320/508 (63.0%)	337/511 (65.9%)
<i>E. coli</i>	230/355 (64.8%)	229/352 (65.1%)
<i>K. pneumoniae</i>	35/65 (53.8%)	52/78 (66.7%)
<i>P. mirabilis</i>	23/42 (54.8%)	21/31 (67.7%)
<i>E. cloacae</i>	7/12 (58.3%)	4/8 (50.0%)
Resistant Enterobacterales Phenotypes		
ESBL+	57/105 (54.3%)	53/85 (62.4%)
FQ-NS	86/159 (54.1%)	90/146 (61.6%)
TMP-SMX-R	96/168 (57.1%)	108/168 (64.3%)

*Only pathogens with ≥ 5 isolates in either treatment group are presented.

ESBL+ = Extended-spectrum β-lactamase-producing; FQ-NS = fluoroquinolone-nonsusceptible; TMP-SMX-R = trimethoprim-sulfamethoxazole-resistant.

ADAPT-PO Met the Primary Efficacy Endpoint



Oral TBP-PI-HBr was non-inferior to IV ertapenem in overall response at TOC

159. As stated above, the October 16, 2020 Press Release also included a link to the 2020 IDSA ID Week Posters. One of the presentation posters, number 1695 titled “Tebipenem: An Oral Carbapenem With Activity Against Multi-Drug Resistant Urinary Tract Infection Isolates of Escherichia Coli Collected From US Medical Centers During 2019” (the “2020 IDSA ID Week Poster 1695”), discussed tebipenem’s ability to fight E. coli in UTIs in the United States. 2020 IDSA ID Week Poster 1695 also boasted that “Tebipenem is an oral carbapenem that has recently demonstrated non-inferiority to IV ertapenem for the treatment of cUTI” and “Tebipenem represents a new oral option for cUTIs in an era of ESBL-mediated co-resistance to existing oral agents.”

160. Another of the 2020 IDSA ID Week Posters, number 1304 titled “Characterization of Tebipenem Pivoxil Hydrobromide Pharmacokinetics – Pharmacodynamics in a Neutropenic Murine Acute Pyelonephritis Model” (the “2020 IDSA ID Week Poster 1304”) discussed tebipenem’s efficacy and its pharmacokinetics. 2020 IDSA ID Week Poster 1304 stated that

Tebipenem HBr “is a carbapenem with broad-spectrum activity against Gram-positive and -negative bacteria that is being developed for the treatment of patients with complicated urinary tract infections.”

November 5, 2020 Press Release

161. On November 5, 2020, Spero issued a press release that announced the Company’s financial performance for the third quarter ended September 30, 2020. The press release contained a statement from Defendant Mahadevia, stating that “[w]e made significant clinical progress in the third quarter with the announcement that the ***ADAPT-PO Trial met its primary endpoint***.” He also stated that the Company is “excited by the positive results seen in the ADAPT-PO trial” and that the results “highlight the potential benefit oral tebipenem HBr could offer to patients with cUTI.”

162. The press release also reported that the Company’s third quarter of 2020 net loss was \$18.9 million, or \$0.86 per common share, with total revenue of \$4 million. For the same period one year prior, Spero’s net loss was \$17.7 million, or \$0.95 per share, with total revenue of \$4.6 million. The press release also reported that the Company had \$127.2 million in cash and cash equivalents as of September 30, 2020.

November 5, 2020 Earnings Call

163. On November 5, 2020, Spero held an earnings call with analysts and investors to discuss the Company’s third quarter of 2020 financial results. During the call, both Defendant Mahadevia and Interim CEO Stephen J. DiPalma (“DiPalma”) spoke to analysts and investors. During his prepared statement, Defendant Mahadevia stated that the Company’s “***ADAPT-PO Phase 3 trial met its primary endpoint*** with data demonstrating that oral tebipenem HBr is non-inferior to IV or dependent for the treatment of complicated urinary tract infections and acute pyelonephritis.” He also stated that “positive results from this trial ... are quite noteworthy as they

show tebipenemHBr can provide the convenience of an oral therapy without making any compromises on clinical response, safety or tolerability.”

164. Defendant Mahadevia also told investors that the ADAPT-PO Trial “results represent an important achievement not only for Spero, but also for the broader industry and our patients.” Defendant Mahadevia concluded his prepared statement by saying, “[a]s previously discussed with FDA, positive results in the single, well-controlled pivotal trial could be sufficient to support the approval of a new drug application or NDA for tebipenem HBr” and repeating that Spero “continue[s] to *expect to make an NDA submission to the FDA in the second quarter of 2021.*”

165. In answering a question from an analyst about COVID-19’s impact on the ADAPT-PO Trial, Defendant Mahadevia stated that “[f]ortunately, for us we have been able to, with an excellent clinical operations team, manage that well and *we’re able to deliver ADAPT-PO on time with high-quality data*, number one. And number two, also the Phase 1 studies that were outstanding for the filing of the NDA.”

166. In answering a question from an analyst about Spero’s remaining tasks before filing the NDA, Defendant Mahadevia stated that “the three parts to filing the NDA,” including the ADAPT-PO Trial data, “are on track as it relates to our overall timeline for NDA.”

November 5, 2020 Form 10-Q

167. On November 5, 2020, the Company filed its quarterly report with the SEC for the period ended September 30, 2020 (the “3Q20 10-Q”). The 3Q20 10-Q was signed by Defendant Mahadevia and non-party DiPalma, and contained certifications pursuant to Rule 13a-14(a) and 15d-14(a) under the Exchange Act and the Sarbanes-Oxley Act of 2002 (“SOX”) signed by Defendants Mahadevia and non-party DiPalma attesting to the accuracy of the financial

statements contained therein, the disclosure of any material changes to the Company's internal controls, and the disclosure of any fraud committed by the Company, its officers, or its directors.

168. The 3Q20 10-Q described Tebipenem HBr as the Company's "most advanced product candidate" that is "designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections." In section of the 3Q20 10-Q titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," the 3Q20 10-Q stated that the Company's "ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates." The 3Q20 10-Q also stated that "[t]reatment with effective orally administrable antibiotics may prevent hospitalizations for serious infections and enable earlier, more convenient and cost-effective treatment of patients after hospitalization."

169. The 3Q20 10-Q emphasized "positive topline results for the Phase 3 ADAPT-PO clinical trial of oral tebipenem HBr in [cUTI] and [AP]" which "***met the primary endpoint demonstrating statistical non-inferiority versus IV ertapenem.***" The 3Q20 10-Q also stated that "comparative safety data from the 1,372 hospitalized adult patients who enrolled in the trial suggest that tebipenem HBr was well-tolerated, with a safety profile similar to that of ertapenem." From these results, the Company "anticipate[d] ***submitting a New Drug Application for tebipenem HBr to the FDA in the second quarter of 2021.***"

170. The 3Q20 10-Q reported a quarterly net loss of \$18.9 million, or \$0.86 per share, with revenues of \$4 million (of which \$3.76 million was reimbursement for qualifying expenses under the BARDA contract for Tebipenem HBr) for the third quarter of 2020. The 3Q20 10-Q additionally reported that Spero spent \$10.6 million on research and development for Tebipenem

HBr in the third quarter of 2020, and that Spero had \$127.2 million in cash, cash equivalents and marketable securities as of September 30, 2020.

November 13, 2020 Prospectus Supplement

171. On November 13, 2020, Spero filed a Prospectus Supplement on Form 424B5 with the SEC (the “November 13, 2020 Prospectus Supplement”), supplementing the Company’s already filed December 3, 2018 Prospectus. The November 13, 2020 Prospectus Supplement characterized Tebipenem HBr as the Company’s “most advanced product candidate” that “is designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections.” The November 13, 2020 Prospectus Supplement also stated that Spero’s “novel product candidates, if successfully developed and approved, would have a meaningful patient impact and significant commercial applications for the treatment of MDR infections in both the community and hospital settings.”

November 18, 2020 Stifel Healthcare Conference

172. On November 18, 2020, the Company presented at the 2020 Stifel Healthcare Conference by utilizing a slide-show presentation titled “Spero Therapeutics Corporate Presentation” (the “November 18, 2020 Stifel Healthcare Conference Slides”). The November 18, 2020 Stifel Healthcare Conference Slides called the ADAPT-PO Trial a “landmark” study that produced “Robust” results. The November 18, 2020 Stifel Healthcare Conference Slides also repeated that the ADAPT-PO Trial’s results supported an NDA submission for Tebipenem HBr, stating, “***ADAPT-PO Phase 3 met its primary endpoint in landmark trial – Oral tebipenem HBr demonstrated noninferiority to IV ertapenem in cUTI and AP, Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin).***”

173. The November 18, 2020 Stifel Healthcare Conference Slides also stated that “Tebipenem HBr, if approved as the first oral carbapenem, could allow appropriate patients the opportunity to receive treatment in the community setting,” and “Tebipenem has the Potential to be a Highly Differentiated Therapy, if Approved.”

174. The November 18, 2020 Stifel Healthcare Conference Slides emphasized that ***“Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem...at margin of -12.5%”*** based on analyses of the micro-ITT population and that the “Results were similar between treatment arms across all subgroups of patients.”

175. The November 18, 2020 Stifel Healthcare Conference Slides also stated that “ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes: Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms.” The November 18, 2020 Stifel Healthcare Conference Slides also repeated that Tebipenem HBr’s NDA was on schedule because of the ADAPT-PO Trial, describing the study as the “One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions” and stating, ***“Positive ADAPT-PO Trial Results Support an NDA submission in 2Q21.”***

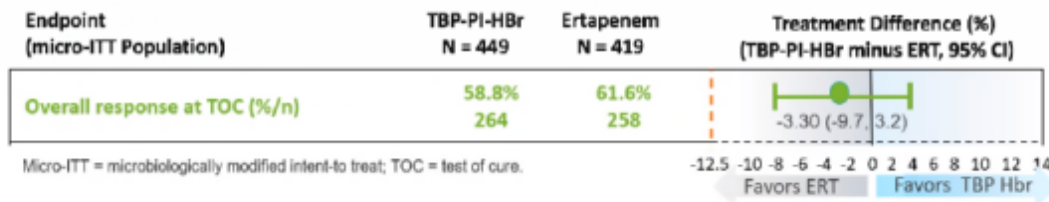
176. The November 18, 2020 Stifel Healthcare Conference Slides also discussed Spero’s funding in relation to Tebipenem HBr’s NDA, stating that the Company was “Funded into the first quarter of 2022, through the NDA submission and the approval process for tebipenem HBr,” and “BARDA/DTRA non-dilutive funding award for tebipenem HBr [was] up to \$56.7M” with “additional awards and alliances provid[ing] funding for the pipeline.” The November 18, 2020 Stifel Healthcare Conference Slides included the following slides, in relevant part:

ADAPT-PO Met Its Primary Efficacy Endpoint

Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem

ADAPT-PO primary endpoint:

Clinical cure + microbiological eradication at test-of-cure in micro-ITT population



Demonstrated non-inferiority at margin of -12.5%*

Results were similar between treatment arms across all subgroups of patients



* The trial at 95% confidence interval (CI) achieved success (a -9.7 NI margin) within the original -10% NI margin
TBP-PI-HBr, tebipenem HBr; ERT, ertapenem

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ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes

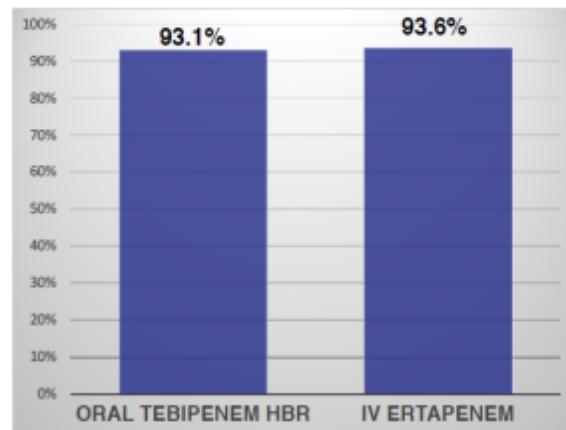
Clinical cure rate is a key determinant in routine clinical management of cUTI patients

Clinical cure rates at test-of cure (TOC) for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms

Durable clinical response observed with high clinical cure rates at TOC sustained through late follow-up visit

Median duration of therapy was similar for both treatment groups

Comparable Clinical Cure Rates at TOC



Micro ITT = Microbiological Intent-to-treat

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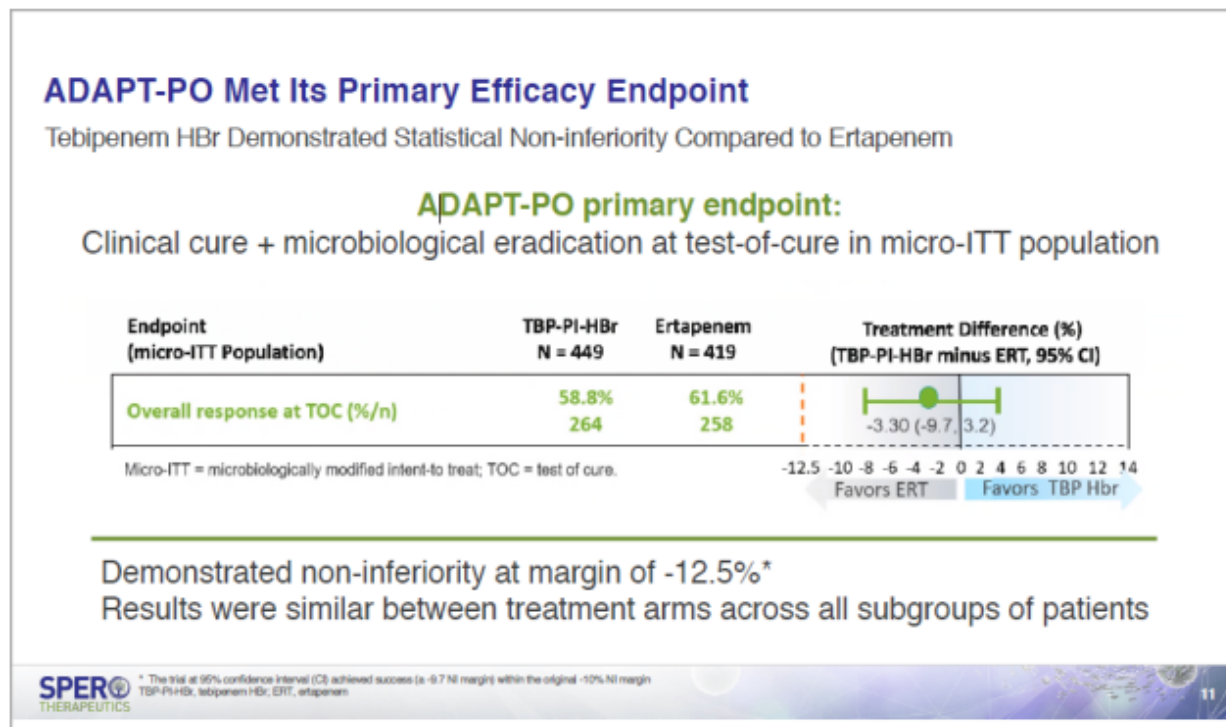
December 3, 2020 Form 8-K

177. On December 3, 2020, Spero filed a Form 8-K with the SEC (the “December 3, 2020 8-K”). The December 3, 2020 8-K announced that “The Company expects to complete the planned submission of its NDA for tebipenem HBr during the second half of 2021.” The December 3, 2020 8-K also stated that “[T]he Company believes that its existing cash, cash equivalents and marketable securities, together with committed funding from its BARDA contract and other non-dilutive funding commitments, will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2022, including through the submission of the NDA for tebipenem HBr.”

178. Exhibit 99.1, which contained a slide presentation for investors titled “Spero Therapeutics Corporate Presentation Evercore ISI HealthCONx Conference,” was attached to the December 3, 2020 8-K (the “Evercore Slides”). The Evercore Slides were utilized in corporate presentations, uploaded to Spero’s website, and were disseminated in hardcopy and electronic format. The Evercore Slides boasted that the ADAPT-PO Trial produced “Robust” results and repeated that “*ADAPT-PO Phase 3 met its primary endpoint in landmark trial – Oral tebipenem HBr demonstrated noninferiority to IV ertapenem in cUTI and AP, Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin).*”

179. The Evercore Slides also stated that “Tebipenem HBr, if approved as the first oral carbapenem, could allow appropriate patients the opportunity to receive treatment in the community setting.” The Evercore Slides emphasized that “*Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem...at margin of -12.5%*” based upon analyses of the micro-ITT population and that the “Results were similar between treatment arms across all subgroups of patients.”

180. The Evercore Slides also stated, “ADAPT- PO Key Secondary Endpoints Evaluating Patient Outcomes: Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms.” The Evercore Slides described the ADAPT-PO Trial as the “One well- controlled pivotal trial to form the basis for an NDA submission as per FDA interactions” and stated, “***Positive ADAPT-PO Trial Results Support an NDA submission in 2Q21.***” The Evercore Slides also discussed Spero’s funding in relation to Tebipenem HBr’s NDA, stating that the Company was “Funded into the second quarter of 2022, through the NDA submission for tebipenem HBr” and boasted the “BARDA/DTRA non-dilutive funding award for tebipenem HBr [was] up to \$56.7M” with “additional awards and alliances provid[ing] funding for the pipeline.” The Evercore Slides included the following slides, in relevant part:



ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes

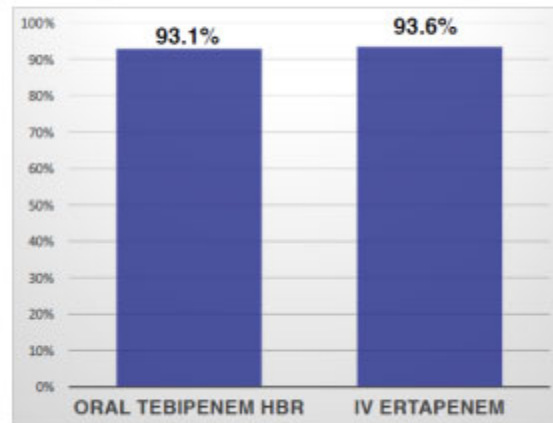
Clinical cure rate is a key determinant in routine clinical management of cUTI patients

Clinical cure rates at test-of cure (TOC) for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms

Durable clinical response observed with high clinical cure rates at TOC sustained through late follow-up visit

Median duration of therapy was similar for both treatment groups

Comparable Clinical Cure Rates at TOC



SPERO Micro ITT = Microbiological Intent-to-treat
THE RAPIDICS

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December 3, 2020 3rd Annual Evercore ISI HealthCONx Conference

181. On December 3, 2020, Defendant Mahadevia represented Spero at the 3rd Annual Evercore ISI HealthCONx Conference, where he gave a presentation on the “successful” ADAPT-PO Trial. During the presentation, Defendant Mahadevia stated that “both from a pharmacokinetic perspective and microbiological perspective and now a clinical perspective, *we’ve shown that tebipenem behaves like a carbapenem in a pill.*” Defendant Mahadevia went on to state the following, in relevant part:

And what we’ve shown is that tebipenem is a carbapenem in a pill. And so we recently unveiled ADAPT-PO which is our Phase 3 study, the first ever of its kind and we compared this all oral regimen in a very sick population with cUTI against an all IV regimen. *We wanted to, both from a payer and a prescriber perspective, show that our oral regimen did the exact same thing as IV. And that is what the study showed both from an efficacy perspective, but also from a tolerability perspective. And, we’re hard at work on the NDA.*

182. During the presentation, an analyst asked Defendant Mahadevia whether there is a need for a gram-negative bacteria treatment for non-hospitalized patients and whether the ESBL+

and other antibiotic-resistant bacteria are causing the need. Defendant Mahadevia replied, “along with ESBL where a typical form of resistance that these UTI bacteria pass to each other, there are a variety of other mechanisms that these bacteria have learned over a period of time to become resistant.”

183. Another analyst asked when Spero would give more information about the NDA and what the next two years from Spero would look like. Defendant Mahadevia replied, “As we noted, you’ll be looking for us to be providing further communication as we go in terms of the cadence of the NDA. *Within that timeframe, we will also have had our pre-NDA discussion with FDA.*”

December 17, 2020 Press Release

184. On December 17, 2020, Spero issued a press release that announced the appointment of Defendant Shukla as the Company’s CFO. In the press release, Defendant Shukla stated, “With positive Phase 3 data for tebipenem HBr in September 2020 [], *Spero is well positioned to realize its clinical, strategic and financial objectives.*”

January 21, 2021 Press Release

185. On January 21, 2021, Spero issued a press release that announced that a patent was issued for the Tebipenem HBr’s crystalline formulation. The press release highlighted “positive” top-line results from the ADAPT-PO Trial. In the press release, Defendant Mahadevia stated, “We remain focused on advancing oral tebipenem HBr towards a potential approval and *look forward to submitting the New Drug Application for tebipenem HBr to the FDA in the second half of 2021.*”

March 11, 2021 Registration Statement

186. On March 11, 2021, Spero filed a Registration Statement on Form S-3 with the SEC (the “March 11, 2021 Registration Statement”) which Defendants Mahadevia, Shukla, Deshpande, Jackson, Pottage, Smith, Thomas, Formela, and Vink signed. The March 11, 2021 Registration Statement boasted that Tebipenem HBr was Spero’s “most advanced product candidate” that “is designed to be the first oral carbapenem-class for use in adults to treat MDR Gram-negative infections” that “may prevent hospitalizations for serious infections and enable earlier, more convenient and cost-effective treatment of patients after hospitalization.”

March 11, 2021 Press Release

187. On March 11, 2021, Spero issued a press release that announced the Company’s financial results for the fourth quarter and 2020 Fiscal Year. In the press release, Defendant Mahadevia stated that among the Company’s major accomplishments for the 2021 Fiscal Year “was our announcement in September 2020 that ***the tebipenem HBr ADAPT-PO Phase 3 clinical trial in complicated urinary tract infection ... met its primary endpoint.***” He also stated that “we look forward to another productive year in 2021, ***as we advance tebipenem HBr towards an NDA submission in the second half of 2021*** and move closer to potentially addressing the unmet needs of the estimated 2.7 million cUTI and AP patients in the United States.”

188. The press release also reported that the Company’s fourth quarter of 2020 net loss and 2020 Fiscal Year net loss was \$18.6 million, or \$0.68 per common share, and \$78.8 million, or \$3.52 per share, respectively. The press release also reported that the fourth quarter of 2020 generated \$1.9 million in revenue and the 2020 Fiscal Year generated \$9.3 million in total revenue. For the same period one year prior, Spero’s net loss for the fourth quarter of 2019 was \$25 million, or \$1.31 per share, and the Company’s net loss for the fiscal year ended December 31, 2019 was \$60.9 million, or \$3.35 per share. The press release reported that the Company had \$127.2 million

in cash and cash equivalents as of September 30, 2020. The press release also reported that the Company had \$126.9 million in cash, cash equivalents and marketable securities as of December 31, 2020.

March 11, 2021 Earnings Call

189. On March 11, 2021, Spero held an earnings call with analysts and investors to discuss the Company's fourth quarter and 2020 Fiscal Year financial results. During the call, both Defendants Mahadevia and Shukla spoke to analysts and investors. During his prepared statement, Defendant Mahadevia stated that the Company's "primary focus remains *tebipenem HBr's advancement towards commercialization following the positive ADAPT-PO Phase 3 trial results* that we reported in September." He elaborated, "[t]hese *results showed that the trial met its primary endpoint with data demonstrating that all oral regimen of tebipenem HBr is non-inferior to an all IV regimen or ertapenem for the treatment of complicated urinary tract infections, or cUTI, and acute pyelonephritis, or AP.*"

190. Defendant Mahadevia also stated the following in his prepared statement, in relevant part:

We chose the design ADAPT-PO as the first head-to-head comparison of an all-oral and all-IV regimen in cUTI specifically to provide a robust result that would give physicians the confidence to prescribe tebipenem HBr to the millions of cUTI and AP patients who would otherwise receive IV therapy. We believe we have done just that as our data show that tebipenem HBr can provide the convenience of an oral therapy without making any compromises on clinical response safety or tolerability. Based on our previous FDA interactions and written communication, positive results from this single well-controlled pivotal trial could be sufficient to support the approval of a new drug application, or NDA, for tebipenem HBr.

191. Defendant Mahadevia further stated that the Company "continue[s] to expect to make an NDA submission to FDA for tebipenem HBr for the treatment of cUTI and AP in the

second half of 2021” and felt “*comfortable with this guidance ... given that the Phase 3 and all supportive Phase 1 trials have been completed.*”

192. During the call, an analyst asked Defendant Mahadevia about Spero’s plans for Tebipenem HBr after the Company receives FDA approval and markets Tebipenem HBr. Defendant Mahadevia replied that the Company is “focused on maximizing the value for tebipenem and cUTI” and depicted the ADAPT-PO Trial as “powerful in its own right.”

March 11, 2021 Form 10-K

193. On March 11, 2021, Spero filed its annual report for the 2020 Fiscal Year on Form 10-K with the SEC (the “2020 10-K”). The 2020 10-K was signed by Defendants Mahadevia, Shukla, Deshpande, Jackson, Pottage, Smith, Thomas, Formela, and Vink and contained SOX certifications signed by Mahadevia and Shukla attesting to its accuracy.

194. The 2020 10-K described Tebipenem HBr as the Company’s “most advanced product candidate” and noted multiple “key attributes” and “advantages” that “support our confidence in tebipenem HBr’s commercial potential.” In a section of the 2020 10-K titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” the 2020 10-K stated that the Company’s “ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates.” The 2020 10-K also emphasized Tebipenem HBr’s safety and efficacy, stating that the drug candidate has the “potential to be a safe and effective treatment for cUTI and other serious and life-threatening infections,” because of “*positive topline data from the single pivotal Phase 3 clinical trial ... that is required for approval of tebipenem HBr* to treat complicated urinary tract infection,” which “*achieved its primary objective, demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous ertapenem*

in the treatment of patients with cUTI and patients with AP, with respect to the primary endpoint of overall response at the test-of-cure, or TOC, visit in the microbiological-intent-to-treat, or micro-ITT, population.”

195. Because of these positive results, the 2020 10-K maintained, the Company forecasted that it would submit the NDA to the FDA in the second half of 2021. The 2020 10-K also stated that “[b]ased on our pre-IND, pre-Phase 3 meeting with the FDA, *we believe that positive results from a single Phase 3 clinical trial of tebipenem in cUTI would support the approval of tebipenem HBr for the treatment of cUTI.*”

196. The 2020 10-K reported 2020 Fiscal Year net loss of \$78.3 million, or \$3.52 per share, with \$9.3 million in total revenue. For the same period one year prior, the Company’s net loss for the fiscal year ended December 31, 2019 was \$60.9 million, or \$3.35 per share. Of the \$9.3 million in total revenue for the 2020 Fiscal Year, \$7.9 million consisted of reimbursement from qualifying expenses under the BARDA contract for Tebipenem HBr. The 2020 10-K additionally reported that Spero spent \$41.9 million on research and development for Tebipenem HBr in the 2020 Fiscal Year. The 2020 10-K further reported that the Company had \$126.9 million in cash, cash equivalents and marketable securities as of December 31, 2020.

March 16, 2021 Oppenheimer 31st Annual Healthcare Conference

197. On March 16, 2021, Defendants Mahadevia and Shukla represented Spero at the Oppenheimer 31st Annual Healthcare Conference, where they gave a presentation on the “landmark” ADAPT-PO Trial. During the presentation, they described the ADAPT-PO Trial’s data results as “Robust” and told investors and analysts that the “*ADAPT-PO Phase 3 met its primary endpoint in landmark trial – Oral tebipenem HBr demonstrated noninferiority to IV ertapenem in cUTI and AP, Overall combined response rate: Oral tebipenem HBr response rate*

of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; - 12.5% NI margin).” They also stated that “Tebipenem HBr, if approved as the first oral carbapenem, could allow appropriate patients the opportunity to receive treatment in the community setting.”

198. Defendants Mahadevia and Shukla utilized a slide deck for the presentation (the “March 16, 2021 Oppenheimer Slides”). The March 16, 2021 Oppenheimer Slides stated that ***“Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem...at margin of -12.5%”*** on analyses of the micro-ITT population and that “Results were similar between treatment arms across all subgroups of patients.” The March 16, 2021 Oppenheimer Slides also told investors and analysts that “ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes: Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms.”

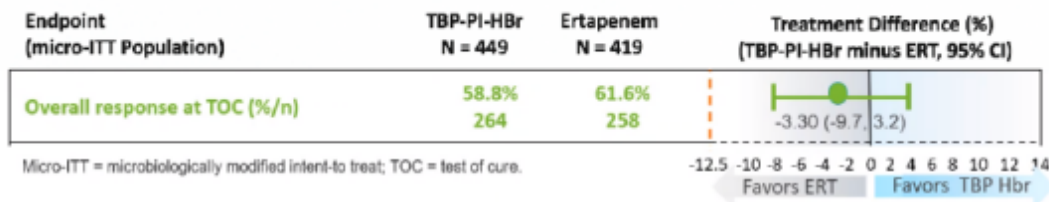
199. The March 16, 2021 Oppenheimer Slides also reassured investors and analysts that the NDA submission remained on time, again stating that the ADAPT-PO Trial is the “One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions,” and further stated, ***“Positive ADAPT-PO Trial Results Support an NDA submission in 2Q21.”*** The slides also discussed the Company’s funding situation, stating that Spero was “Funded into the second quarter of 2022, through the NDA submission for tebipenem HBr,” and “BARDA/DTRA non-dilutive funding award for tebipenem HBr up to \$56.7M” with “additional awards and alliances provid[ing] funding for the pipeline.” The March 16, 2021 Oppenheimer Slides included the following slides, in relevant part:

ADAPT-PO Met Its Primary Efficacy Endpoint

Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem

ADAPT-PO primary endpoint:

Clinical cure + microbiological eradication at test-of-cure in micro-ITT population



Demonstrated non-inferiority at margin of -12.5%*

Results were similar between treatment arms across all subgroups of patients



* The trial at 95% confidence interval (CI) achieved success (a -9.7% margin) within the original -10% NI margin
TBP-PI-HBr, tebipenem HBr; ERT, ertapenem

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ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes

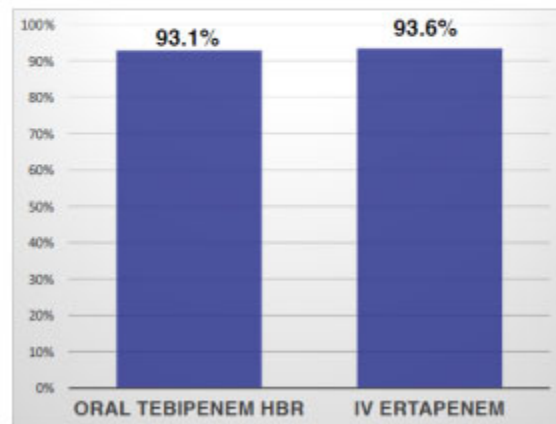
Clinical cure rate is a key determinant in routine clinical management of cUTI patients

Clinical cure rates at test-of cure (TOC) for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms

Durable clinical response observed with high clinical cure rates at TOC sustained through late follow-up visit

Median duration of therapy was similar for both treatment groups

Comparable Clinical Cure Rates at TOC



Micro ITT = Microbiological Intent-to-treat

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May 6, 2021 Press Release

200. On May 6, 2021, Spero issued a press release titled, “Spero Therapeutics Announces First Quarter 2021 Operating Results and Provides Business Update,” that announced

the Company's financial results for the first quarter of 2021. In the press release, Defendant Mahadevia stated that "[w]e recently completed a pre-NDA meeting for tebipenem HBr with the FDA and received feedback indicating that the format and content of the planned data package we intend to include in our NDA will be sufficient to support the submission. This regulatory milestone keeps us on track to submit the NDA in the second half of the year as we work to transition to a commercial-stage organization." The press release further stated the following, in relevant part:

"We are off to a strong start in 2021 and I am very pleased with the progress we have made across our pipeline," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "We recently completed a pre-NDA meeting for tebipenem HBr with the FDA and received feedback indicating that the format and content of the planned data package we intend to include in our NDA will be sufficient to support the submission. This regulatory milestone keeps us on track to submit the NDA in the second half of the year as we work to transition to a commercial-stage organization. Our Phase 3 ADAPT-PO data indicate that, if approved, tebipenem HBr may provide many of the over 2 million cUTI and acute pyelonephritis patients who would typically receive IV therapy the convenience of an oral treatment with comparable efficacy and safety. Replacing IV therapy with an oral option may help avoid unnecessary hospitalizations, delivering substantial value to payers, physicians, and most importantly, patients."

Clinical Highlights and Upcoming Milestones

Tebipenem HBr:

Spero's lead product candidate, tebipenem HBr, has the potential to be the first oral carbapenem antibiotic, if approved, to treat complicated urinary tract infection (cUTI), including acute pyelonephritis (AP). In September 2020, Spero announced positive data from the Phase 3 ADAPT-PO trial showing that oral tebipenem HBr was statistically non-inferior to intravenous ertapenem in the treatment of patients with cUTI and patients with AP.

In March 2021, Spero successfully completed a pre-new drug application (NDA) meeting with the United States Food and Drug Administration (FDA). The purpose of the meeting was to discuss the format and content of Spero's planned NDA submission. Subject to FDA's review of the full submission, Spero and the FDA achieved consensus that the NDA package as described during the course of the meeting would allow for FDA review, consistent with Spero's expectations. Spero remains on track to make the NDA submission to the FDA in the second half of 2021.

201. The press release also reported that the Company's first quarter of 2021 net loss was \$19.4 million, or \$0.66 per common share, with total revenue of \$7.3 million. For the same period one year prior, Spero's net loss was \$23.3 million, or \$1.22 per share, with total revenue of \$1.7 million. The press release also reported that the Company had \$115.7 million in cash, cash equivalents, and marketable securities as of March 31, 2021.

May 6, 2021 Earnings Call

202. On May 6, 2021, Spero held an earnings call with analysts and investors to discuss the Company's first quarter of 2021 financial results. During the call, both Defendants Mahadevia and Shukla spoke to analysts and investors. During his prepared statement, Defendant Mahadevia stated that the Company's "major focus" is "the advancement of tebipenem HBr towards an NDA filing." He went on to say that "***These efforts are supported by the positive Phase 3 ADAPT-PO trial results*** which we reported late last year. These results showed that the trial's primary endpoint was met with demonstrating that an all-oral regimen of tebipenem HBr is not inferior to an all-IV regimen of ertapenem for the treatment of complicated urinary tract infection or cUTI and acute pyelonephritis or AP." Defendant Mahadevia also stressed the Company's communications with the FDA pertaining to the ADAPT-PO Trial and Tebipenem HBr:

Our previous FDA interactions and written communication indicated that positive results from the single well-controlled pivotal trials such as ADAPT-PO could be sufficient to support the approval of a New Drug Application or NDA for tebipenem HBr in the treatment of cUTI and AP.

Today, I'm pleased to report that we recently completed a pre-NDA meeting with the agency and received feedback that was consistent with all of these prior interactions. The FDA has endorsed the structure and form of our planned NDA submission and indicated that the clinical data set and CMC plan that we intend to submit in the NDA package to meet their standards.

This positive regulatory interaction, together with the fact that all of the data we need for submission is in our hands, keep us on track to complete the tebipenem HBr NDA submission in the second half of the year as we previously guided.

203. Defendant Mahadevia also stressed Tebipenem HBr's safety and tolerability in his prepared statement:

Now, in addition to supporting NDA filing, another important goal of the ADAPT-PO trial was to answer the fundamental question that physicians and payers have regarding an oral version of a powerful IV medicine.

And this question is if patients are going to receive oral therapy in place of an IV option, how does the safety and efficacy of the oral agent compare to the IV? We addressed this question by designing ADAPT-PO as the first head-to-head comparison of all-oral versus an all-IV regimen in cUTI.

Specifically, we did not include an IV lead in the oral tebipenem HBr arm nor an oral step-down in the IV ertapenem arm as we wanted to provide physicians with direct evidence that we give them the confidence needed to prescribe tebipenem HBr to the millions of cUTI and AP patients who would otherwise receive IV therapy.

As we have mentioned before, we believe we have done just now as our data show that tebipenem HBr can provide convenience of an oral therapy without any compromises on clinical response, safety, or tolerability. And based on these compelling data, we believe tebipenem HBr if approved, would be an important treatment option for the over 2 million cUTI and AP patients in the US alone each year who are resistant to current available oral therapies.

204. During the unscripted, Q and A part of the earnings call, an analyst asked Defendant Mahadevia "in your pre-NDA meeting, did any either review issues or potential review issues arise? Other - were there any surprises I guess from your expectations going in or from your questions asked of the agency?" Defendant Mahadevia replied:

In short Ritu, there were no surprises from the preNDA discussion. And I reiterate the most important takeaways, which is on the basis of that meeting we're on track to submit the NDAs per our guidance in the second half of the year. And that the FDA endorsed the structure and form of our planned submission and also the data set and the CMC plan that we've communicated publicly before. So we're pleased with the outcome of that meeting.

205. Also during the Q and A part of the earnings call, an analyst asked Defendant Mahadevia whether the FDA's strain on resources due to COVID-19 might negatively impact Spero's NDA submission. Defendant Mahadevia replied, "the fact that we have a leg up and a head start in that *the medicine that we've been developing has been on the market in Japan for 10 years, gives us a lot of confidence about the path forward.*"

May 6, 2021 Form 10-Q

206. On May 6, 2021, the Company filed its quarterly report with the SEC for the period ended March 31, 2021 (the "1Q21 10-Q"). The 1Q21 10-Q was signed by Defendants Mahadevia and Shukla and contained SOX certifications signed by Defendants Mahadevia and Shukla attesting to its accuracy.

207. The 1Q21 10-Q described Tebipenem HBr as the Company's "most advanced product candidate" that is "designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections." In a section of the 1Q21 10-Q titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," the 1Q21 10-Q stated that the Company's "ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates." The 1Q21 10-Q referenced the Company's March 25, 2021 meeting with the FDA before NDA submission, stating that the meeting was held to "to discuss format and content of the submission" which produced a "consensus that the package as described would allow review of the NDA." Consequently, the 1Q21 10-Q reported that Spero "anticipate[d] submitting an NDA for tebipenem HBr to the FDA in the second half of 2021."

208. The 1Q21 10-Q reported a quarterly net loss of \$19.4 million, or \$0.66 per share, with revenues of \$7.3 million (of which \$6.3 million was reimbursement for qualifying expenses

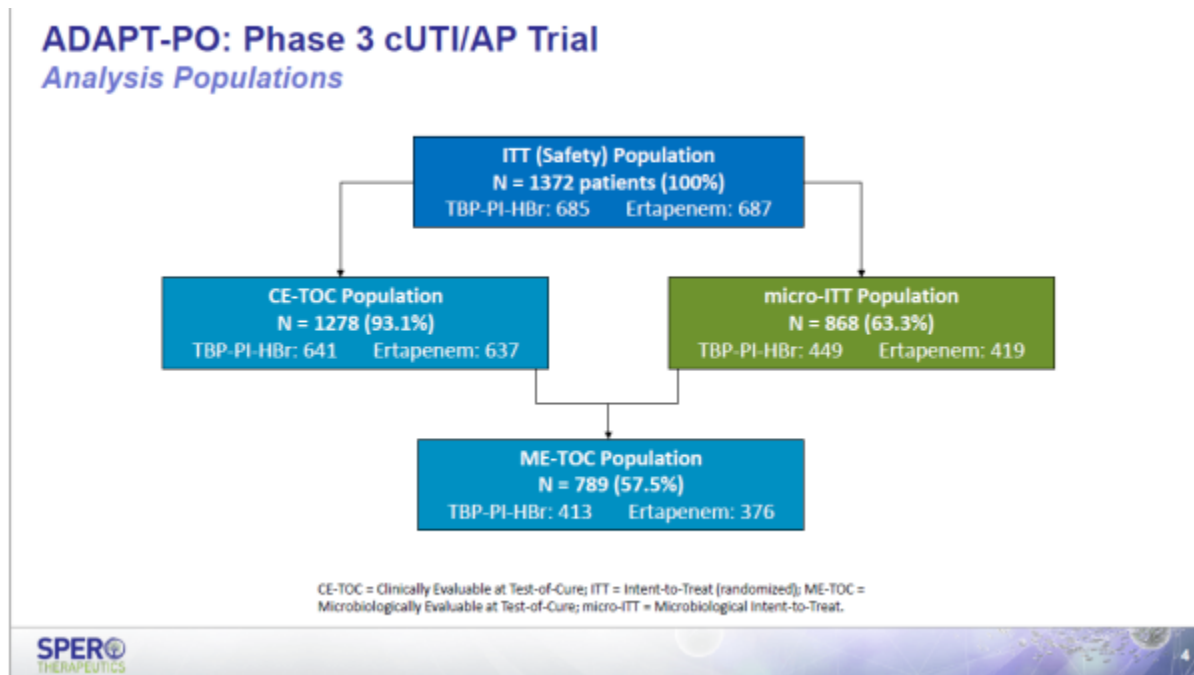
under the BARDA contract for Tebipenem HBr) for the first quarter of 2021. The 1Q21 10-Q additionally reported that Spero spent \$10.1 million on research and development for Tebipenem HBr in the first quarter of 2021, and that Spero had \$115.7 million in cash, cash equivalents and marketable securities as of March 31, 2021.

May 22, 2021 Making a Difference in Infectious Disease Conference

209. On or around May 22, 2021, Spero gave a presentation at the 2021 Making a Difference in Infectious Disease Conference (“MADID Conference”). As part of the presentation, the Company used a slideshow titled “***Oral Tebipenem is Non-Inferior to IV Ertapenem in Complicated Urinary Tract Infection (cUTI) and Acute Pyelonephritis (AP): Results From the Pivotal ADAPT-PO Study***” (the “2021 MADID Conference Slides”). The 2021 MADID Conference Slides were previously used during a prior Spero presentation given at the aforementioned IDWeek 2020 Conference held on October 16, 2020.

210. The 2021 MADID Conference Slides contained the micro-ITT population data, percentages of micro-ITT patients along with breakdowns between gram-negative and gram-positive bacteria and stated the per-pathogen microbiological eradication at test-of-cure for Enterobacterales (gram-negative bacteria). Specifically, the 2021 MADID Conference Slides stated that Tebipenem HBr had a per-pathogen microbiological eradication at test-of-cure for Enterobacterales of 63.0% percent, compared to 65.9% for IV ertapenem. Based upon this data, the 2021 MADID Conference Slides stated that “***ADAPT-PO Met the Primary Efficacy Endpoint***” and that “***Oral TBP-PI-HBr was non-inferior to IV ertapenem in overall response at TOC.***” The slides also emphasized the ADAPT-PO Trial’s data by stating that “Oral TBP-PI-HBr (600mg PO q8h) was non-inferior to ertapenem (1g IV q24h) in the treatment of hospitalized adult patients with cUTI/AP,” “ADAPT-PO achieved all primary and secondary objectives,” and “These

effects were seen consistently across patient subsets.” The 2021 MADID Conference Slides also touted the NDA, stating that “Spero expects that data from this single pivotal trial will support submission of an NDA.” The 2021 MADID Conference Slides contained the following slides, in relevant part:



ADAPT-PO: Phase 3 cUTI/AP Trial

Uropathogens Isolated from Urine and/or Blood at Baseline (micro-ITT)

Baseline Pathogen*	TBP-PI-HBr (N=449)	Ertapenem (N=419)	Total (N=868)
Enterobacterales	397 (88.4%)	386 (92.1%)	783 (90.2%)
<i>Escherichia coli</i>	287 (63.9%)	270 (64.4%)	557 (64.2%)
<i>Klebsiella pneumoniae</i>	53 (11.8%)	71 (16.9%)	124 (14.3%)
<i>Proteus mirabilis</i>	35 (7.8%)	23 (5.5%)	58 (6.7%)
<i>Enterobacter cloacae</i>	11 (2.4%)	8 (1.9%)	19 (2.2%)
<i>Citrobacter freundii</i>	4 (0.9%)	3 (0.7%)	7 (0.8%)
<i>Citrobacter koseri</i>	3 (0.7%)	4 (1.0%)	7 (0.8%)
<i>Klebsiella oxytoca</i>	4 (0.9%)	3 (0.7%)	7 (0.8%)
<i>Providencia rettgeri</i>	4 (0.9%)	3 (0.7%)	7 (0.8%)
<i>Klebsiella variicola</i>	2 (0.4%)	4 (1.0%)	6 (0.7%)
<i>Serratia marcescens</i>	4 (0.9%)	2 (0.5%)	6 (0.7%)
<i>Morganella morganii</i>	4 (0.9%)	1 (0.2%)	5 (0.6%)
Gram-positive cocci	76 (16.9%)	51 (12.2%)	127 (14.6%)
<i>Enterococcus faecalis</i>	58 (12.9%)	36 (8.6%)	94 (10.8%)
<i>Staphylococcus aureus</i>	5 (1.1%)	8 (1.9%)	13 (1.5%)
<i>S. saprophyticus</i>	4 (0.9%)	6 (1.4%)	10 (1.2%)
<i>Enterococcus faecium</i>	5 (1.1%)	2 (0.5%)	7 (0.8%)

*Only pathogens representing ≥ 5 isolates across both treatment groups are presented.

- 90% patients in micro-ITT were infected with Enterobacterales
- Infections caused by resistant Enterobacterales strains were common

Enterobacterales Resistance phenotype ¹	TBP-PI-HBr	Ertapenem
ESBL+	26.5%	22.0%
FQ-non-susceptible	40.2%	37.8%
TMP-SMX-resistant	42.4%	43.5%

¹ Per CLSI screening criteria: ESBL+ = ceftazidime MIC ≥ 2 µg/mL; fluoroquinolone (FQ)-non-susceptible = levofloxacin MIC ≥ 1 µg/mL; trimethoprim-sulfamethoxazole (TMP/SMX)-resistant = TMP-SMX MIC ≥ 4/76 µg/mL.

ADAPT-PO: Phase 3 cUTI/AP Trial

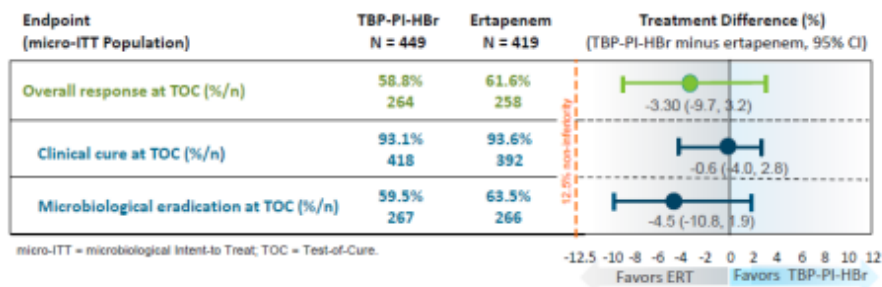
Per-Pathogen Microbiological Eradication at TOC (micro-ITT)

Baseline Pathogen	TBP-PI-HBr N=449 % (n/N1)	Ertapenem N=419 % (n/N1)
Enterobacterales*	320/508 (63.0%)	337/511 (65.9%)
<i>E. coli</i>	230/355 (64.8%)	229/352 (65.1%)
<i>K. pneumoniae</i>	35/65 (53.8%)	52/78 (66.7%)
<i>P. mirabilis</i>	23/42 (54.8%)	21/31 (67.7%)
<i>E. cloacae</i>	7/12 (58.3%)	4/8 (50.0%)
Resistant Enterobacterales Phenotypes		
ESBL+	57/105 (54.3%)	53/85 (62.4%)
FQ-NS	86/159 (54.1%)	90/146 (61.6%)
TMP-SMX-R	96/168 (57.1%)	108/168 (64.3%)

*Only pathogens with ≥ 5 isolates in either treatment group are presented.

ESBL+ = Expanded-spectrum β-lactamase-producing; FQ-NS = fluoroquinolone-nonsusceptible; TMP-SMX-R = trimethoprim-sulfamethoxazole-resistant.

ADAPT-PO Met the Primary Efficacy Endpoint



Oral TBP-PI-HBr was non-inferior to IV ertapenem in overall response at TOC



211. Spero also presented a poster titled “Tebipenem: An Oral Carbapenem With Activity Against Multi-Drug Resistant Urinary Tract Infection Isolates of Escherichia Coli Collected From US Medical Centers During 2019” at the 2021 MADID Conference (the “2021

MADID Poster”). The 2021 MADID Poster addressed Tebipenem HBr’s ability to fight E. Coli from data collected from UTIs in the United States and suggested that the ADAPT-PO Trial determined that Tebipenem HBr’s ability to fight off E. Coli was on par with IV ertapenem, stating *“Tebipenem is an oral carbapenem that has recently demonstrated non-inferiority to IV ertapenem for the treatment of cUTI”* and “Tebipenem represents a new oral option for cUTIs in an era of ESBL-mediated co-resistance to existing oral agents.”

July 1, 2021 Form 8-K and Press Release

212. On July 1, 2021, Spero filed a Form 8-K with the SEC that announced a \$40 million equity investment from Pfizer Inc. and a licensing agreement for another of the Company’s drug candidates undergoing a Phase 1 trial, SPR206. Attached to the Form 8-K was a press release contained in Exhibit 99.1. The press release, officially dated for the previous day, June 30, 2021, stated that “Spero intends to use the proceeds from the equity investment to prepare for the potential approval and launch of tebipenem HBr.” Defendant Mahadevia stated in the press release that “[t]he newly announced equity investment will provide us with valuable capital and financial flexibility as we [among other things,] work towards an NDA filing for tebipenem HBr.”

213. The statements referenced above in ¶¶ 156-212 were materially false and misleading, and failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants willfully or recklessly made false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval; (3) Spero faced an unusually high amount of questions and inquiries from the

FDA before and after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company's workforce and a shift in the Company's focus; (6) due to the foregoing, Spero's reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed to maintain adequate internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

July 6, 2021 Proxy Statement

214. On July 6, 2021, the Company filed the 2021 Proxy Statement with the SEC. Defendants Mahadevia, Deshpande, Formela, Jackson, Pottage, Smith, Thomas, and Vink solicited the 2021 Proxy Statement filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.

215. The 2021 Proxy Statement called for Company shareholders to vote to, *inter alia*: (1) elect Defendants Jackson, Pottage, and Smith to the Board; (2) ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2021; (3) approve amendments to Spero's 2017 Stock Incentive Plan (the "Plan Proposal"); and (4) approve an amendment to Spero's Amended and Restated Certificate of Incorporation to increase the total number of shares of common stock authorized for issuance thereunder from 60,000,000 shares to 120,000,000 shares. The misrepresentations and omissions set forth herein were material to shareholders in voting on electing Defendants Jackson, Pottage, and Smith to the Board and approving the Plan Proposal. Shareholders would not have approved the Plan Proposal or the election of Defendants Jackson,

Pottage, and Smith to the Board had they been informed of the true financial state of the Company and the wrongdoing alleged herein.

216. The purpose of the Plan Proposal was to “encourage ownership of Shares by Employees and directors of and certain Consultants to the Company and its Affiliates in order to attract and retain such people.” The 2021 Proxy Statement further stated that “We believe our future success continues to depend in part on our ability to attract, motivate and retain high quality employees and directors; thus, our ability to provide equity-based and incentive-based awards under the Amended 2017 Plan is critical to achieving this success.” Regarding the Plan Proposal, the 2021 Proxy Statement also stated the following, in relevant part:

We believe our future success continues to depend in part on our ability to attract, motivate and retain high quality employees and directors; thus, our ability to provide equity-based and incentive-based awards under the Amended 2017 Plan is critical to achieving this success. Without adequate shares available for equity compensation, we might be compelled to increase significantly the cash component of our employee compensation, which would consume cash needed to advance our clinical programs and to launch and commercialize tebipenem HBr, which are the drivers of value for our stockholders. Replacing equity awards with cash may not necessarily align employee and director compensation interests with the investment interests of our stockholders. Further, a lack of equity compensation to offer would put us at competitive disadvantage to recruit and retain employees, and would hamper our ability to align our compensation with long-term stockholder value creation.

217. With respect to the Company’s Code of Conduct, the 2021 Proxy Statement stated:

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, including our chief executive officer and chief financial and accounting officers. [...] Disclosure regarding any amendments to, or waivers from, provisions of the Code of Business Conduct and Ethics that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K[.]

218. Regarding the Board’s “Role in Risk Oversight,” the 2021 Proxy Statement stated:

Our Board of Directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our Board of Directors performs this oversight role by using several different levels of review.

In connection with its reviews of the operations and corporate functions of our Company, our Board of Directors addresses the primary risks associated with those operations and corporate functions. In addition, our Board of Directors reviews the risks associated with the Company's business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our board committees also oversees the management of the Company's risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Executive Officer reports to the Audit Committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its risk management role, our Audit Committee meets privately with representatives from our independent registered public accounting firm and our Chief Executive Officer. The Audit Committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks, and reports to our Board of Directors regarding these activities.

219. Defendants Mahadevia, Deshpande, Formela, Jackson, Pottage, Smith, Thomas, and Vink caused the 2021 Proxy Statement to be false and misleading by failing to disclose that: (1) though the Company claimed its directors and officers adhere to the Code of Conduct and that it would disclose waivers of the policy, the Individual Defendants violated the Code of Conduct either without waivers or without such waivers being disclosed; and (2) the Board and its committees were not properly exercising their risk oversight functions, including their review of the risk exposures described, as evidenced by the occurrence of the wrongdoing alleged herein, which involved members of the Board.

220. In addition, the 2021 Proxy Statement was materially false and misleading, and failed to disclose material facts necessary to make the statements made not false and misleading, because the 2021 Proxy Statement failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval;

(3) Spero faced an unusually high amount of questions and inquiries from the FDA before and after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company's workforce and a shift in the Company's focus; (6) due to the foregoing, Spero's reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed to maintain adequate internal controls.

221. As a result of Defendants Mahadevia, Deshpande, Formela, Jackson, Pottage, Smith, Thomas, and Vink causing the 2021 Proxy Statement to be false and misleading, Company shareholders voted, *inter alia*, to: (1) elect Defendants Jackson, Pottage, and Smith to the Board, allowing them to continue breaching their fiduciary duties to the Company; (2) ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2021; (3) approve the Plan Proposal; and (4) approve an amendment to Spero's Amended and Restated Certificate of Incorporation to increase the total number of shares of common stock authorized for issuance thereunder from 60,000,000 shares to 120,000,000 shares.

July 13, 2021 Ladenburg Thalmann Healthcare Conference

222. On July 13, 2021, Defendant Mahadevia represented Spero at the Ladenburg Thalmann Healthcare Conference during which he gave a presentation on Tebipenem HBr and the "landmark" ADAPT-PO Trial. In his prepared statement, Defendant Mahadevia stated that Tebipenem HBr "brings the power of IV therapy we've been using for patients for over a decade into pill form" and that "*in a first of its kind Phase III study[], oral tebipenem, demonstrated comparable efficacy and tolerability to the gold standard for complicated urinary tract*

infections, which is IV ertapenem.” Defendant Mahadevia also stressed the success of the testing methods used during the ADAPT-PO Trial, stating that “Not only was it compared against an IV, but it was compared in a two-part test of signs and microbiological threshold, and it was compared after you waited 7 to 10 days after the last dose where the bugs might have had an opportunity to grow back,” and “it *had to be comparable where the data were tight enough that the lower bound of this confidence interval was [within 12.5% non-inferiority].*”

223. Defendant Mahadevia also declared that “we have the data in hand to submit our NDA,” “[w]e expect completion of the NDA in the second half of the year,” and “Tebipenem has received fast-track designation, and that means an eight-month review timeline once we’ve submitted.”

224. Importantly, Defendant Mahadevia told investors and analysts that the ADAPT-PO Trial produced data results that supported FDA approval based on meetings Spero had with the FDA, stating, “we’ve had a successful pre-NDA meeting with FDA,” “[w]e’ve confirmed that the data we have in this one well-controlled pivotal trial is the data that’s necessary for the approval of tebipenem,” and “we’re looking forward to our continued collaborative dialogue with our colleagues at FDA.”

225. Defendant Mahadevia further spoke about Spero’s financial condition, telling investors and analysts that Spero had \$115 million in cash as of the first quarter of 2021, not including the \$40 million Pfizer deal. He further told investors and analysts that the Company was funded through the second half of 2022 due in part to the government funding Spero received through BARDA/DTRA and the NIH.

226. During the presentation, Defendant Mahadevia utilized a slideshow (the “2021 Ladenburg Conference Slides”) that described the ADAPT-PO Trial as a “landmark” study that

produced “Robust” results. The 2021 Ladenburg Conference Slides also stated that the “ADAPT-PO Met Primary Endpoint,” “***Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin).***”

227. The 2021 Ladenburg Conference Slides also stated that “Tebipenem HBr, as the first oral carbapenem, could allow appropriate patients the opportunity to receive treatment in the community setting.” The slides maintained that “***Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem...at margin of -12.5%***” based on analyses of the micro-ITT Population and that the “Results were similar between treatment arms across all subgroups of patients.”

228. The 2021 Ladenburg Conference Slides also stated that “ADAPT- PO Key Secondary Endpoints Evaluating Patient Outcomes: Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms.” The slides repeated that the ADAPT-PO Trial was the “One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions” and the NDA submission was still on time as previously stated, representing that “***Positive ADAPT-PO Trial Results Support an NDA submission in 2H21.***”

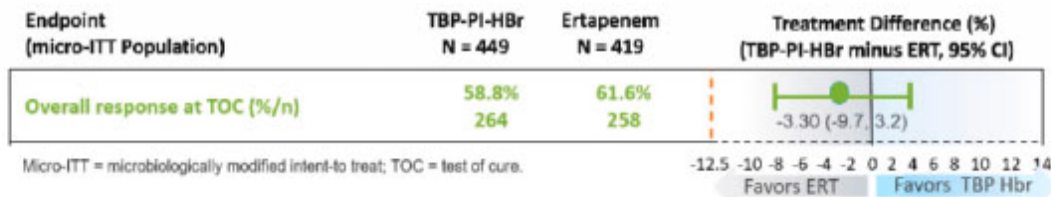
229. The 2021 Ladenburg Conference Slides also stated that “With the recently announced (6/30/2021) \$40M transaction with Pfizer, Spero is funded into the second half of 2022,” “BARDA/DTRA non-dilutive funding award for tebipenem HBr up to \$56.7M” with “additional awards and alliances provid[ing] funding for the pipeline,” and that “Tebipenem HBr [Was] Well Positioned to Recognize Significant Market Opportunity.” The 2021 Ladenburg Conference Slides contained the following slides, in relevant part:

ADAPT-PO Met Its Primary Efficacy Endpoint

Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem

ADAPT-PO primary endpoint:

Clinical cure + microbiological eradication at test-of-cure in micro-ITT population



Demonstrated non-inferiority at margin of -12.5%*

Results were similar between treatment arms across all subgroups of patients



* The trial at 95% confidence interval (CI) achieved success (a -9.7% margin) within the original -10% NI margin
TBP-PI-HBr, tebipenem HBr; ERT, ertapenem

11

ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes

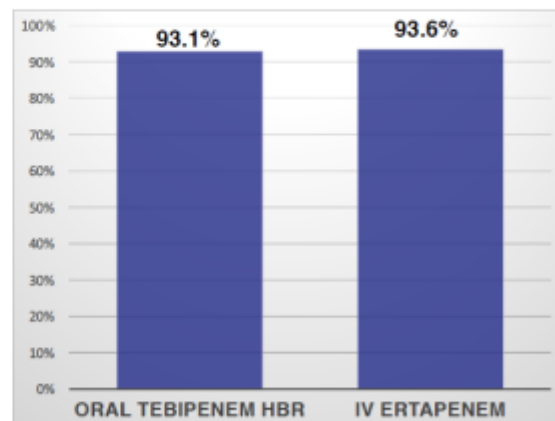
Clinical cure rate is a key determinant in routine clinical management of cUTI patients

Clinical cure rates at test-of cure (TOC) for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms

Durable clinical response observed with high clinical cure rates at TOC sustained through late follow-up visit

Median duration of therapy was similar for both treatment groups

Comparable Clinical Cure Rates at TOC



Micro-ITT = Microbiological Intent-to-treat

12

July 13, 2021 Biotech 2050 Podcast

230. On July 31, 2021, Defendant Mahadevia appeared as a guest on the Biotech 2050 Podcast. During his appearance, he spoke about the ADAPT-PO Trial and Tebipenem HBr.

Specifically, he stated that Tebipenem HBr “*has the same potency as an IV but it’s in a pill form [a]nd, you know, we’ve been through a Phase 3 study which shows when you put it head-to-head against an IV carbapenem it does the job.*” Defendant Mahadevia also emphasized Spero’s forecast for submitting the NDA, saying that “we’re on the cusp now of filing for our FDA approval and looking to get that drug launched in the US.”

August 5, 2021 Press Release

231. On August 5, 2021, Spero issued a press release titled, “Spero Therapeutics Announces Second Quarter 2021 Operating Results and Provides Business Update,” announcing its operating results for the period ended June 30, 2021, as well as updates on Tebipenem HBr. Specifically, Defendant Mahadevia stated that the Company achieved key milestones for future success and that the Company’s focus remained on moving forward with Tebipenem HBr towards an NDA filing. The press release stated, in relevant part:

“During the second quarter, we achieved key milestones which has us well positioned for future success, as we work to submit the tebipenem HBr NDA, transition to a commercial organization, and advance our clinical-stage pipeline,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “These accomplishments were bolstered by the recent \$40 million equity investment from Pfizer Inc., along with their licensing agreement for SPR206. These agreements provide important external validation for our broader corporate strategy and demonstrate the depth and value of our early-stage programs.”

Dr. Mahadevia continued, “Looking forward, our primary focus is to advance tebipenem HBr towards an NDA filing this year, which moves us closer to providing an oral treatment for potentially millions of patients with complicated urinary tract infections. We expect these activities, together with the advancement of our pipeline programs, to drive sustainable growth in our mission to address crucial unmet medical needs.”

232. The press release also reported that the Company’s second quarter of 2021 net loss was \$18.6 million, or \$0.63 per common share, with total revenue of \$5.1 million. For the same period one year prior, Spero’s net loss was \$17.5 million, or \$0.85 per share, with total revenue of

\$1.7 million. The press release also reported that the Company had \$99.2 million in cash and cash equivalents as of June 30, 2021.

August 5, 2021 Earnings Call

233. On August 5, 2021, Spero held an earnings call with analysts and investors to discuss the Company's second quarter of 2021 financial results. During the call, both Defendants Mahadevia and Shukla spoke to analysts and investors. During his prepared statement, Defendant Mahadevia stated that the Company "remain[s] focused on preparing for the upcoming tebipenem HBr NDA filing." He also discussed, at length, the ADAPT-PO Trial and the NDA submission, stating the following, in relevant part:

I'm pleased to say that our efforts around these interrelated goals have continued to advance on track. On our last call, we shared that we had accumulated all of the data necessary for our NDA submission for tebipenem. Since then, we have been performing all of the required analysis and drafting sections of the NDA, both at the study and summary levels. ***We've seen sustained progress on these fronts, and we're confident that we'll submit the NDA in the fourth quarter.*** This is in line with the guidance provided on our last earnings call for an expected NDA submission during the second half of this year. ***Our efforts around tebipenem HBr are supported both by our strong clinical data and our positive regulatory interactions with FDA.***

The positive Phase III ADAPT-PO trial results reported late last year showed that the trial's primary endpoint was met with data demonstrating that an all-oral regimen of tebipenem HBr is noninferior to an all-IV regimen of ertapenem for the treatment of complicated urinary tract infection, or cUTI, and acute pyelonephritis, or AP.

234. Defendant Mahadevia also discussed the Company's communications with the FDA, stating that Spero is "confident" in the NDA. In relevant part, Defendant Mahadevia stated the following:

Now our previous FDA interactions and written communication indicate that positive results from a single well-controlled pivotal trial such as ADAPT-PO could be sufficient to support the approval of an NDA for tebipenem HBr in the treatment of cUTI and AP. Additionally, through feedback we received from our pre-NDA meeting, the FDA endorsed the structure and form of our planned NDA submission

and indicated that the data set and CMC plan that we intend to submit in the NDA package meet their standards.

We are confident that our tebipenem HBr program will continue to advance its plan as we move through the second half of '21 and into 2022. Based on our positive clinical data and ADAPT-PO's rigorous design, we believe that, if approved, tebipenem HBr will be an important physician treatment option for possibly over 2 million cUTI and AP patients in the U.S. alone who are resistant to currently available oral therapies.

ADAPT-PO was designed as the first head-to-head comparison of an all-oral versus an all-IV regimen in cUTI specifically to provide a robust result that would give physicians confidence to prescribe tebipenem HBr to cUTI and AP patients, who would otherwise be required to receive IV therapy. ***We believe we have done just that as our data show that tebipenem HBr can provide the convenience of an oral therapy without any compromises on clinical response, safety or tolerability.***

235. During the Q and A portion of the call, an analyst asked Defendant Mahadevia about Spero educating the medical community in using Tebipenem HBr. Defendant Mahadevia replied, “we are developing data and publishing it that speaks to the value that tebipenem brings to the health care system, and that is both for the clinicians who are very sensitive to these economics as well as our colleagues in the payer community.”

August 5, 2021 Form 10-Q

236. On August 5, 2021, the Company filed its quarterly report with the SEC for the period ended June 30, 2021 (the “2Q21 10-Q”). The 2Q21 10-Q was signed by Defendants Mahadevia and Shukla and contained SOX certifications signed by Defendants Mahadevia and Shukla attesting to its accuracy.

237. The 2Q21 10-Q described Tebipenem HBr as the Company’s “most advanced product candidate” that is “designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections.” In a section of the 2Q21 10-Q titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” the 2Q21 10-Q stated that the Company’s “ability to generate product revenue sufficient to achieve profitability will

depend heavily on the successful development and eventual commercialization of one or more of our product candidates.” The 2Q21 10-Q also stated that “[t]reatment with effective orally administrable antibiotics may prevent hospitalizations for serious infections and enable earlier, more convenient and cost-effective treatment of patients after hospitalization.”

238. Moreover, the 2Q21 10-Q provided an update on the NDA status, stating that Spero was “currently performing integrated analyses in conjunction with the NDA and drafting section of the NDA both at the study and summary level” and “anticipate[d] the completion of an NDA submission to the FDA in the fourth quarter of 2021.”

239. The 2Q21 10-Q reported a quarterly net loss of \$18.6 million, or \$0.63 per share, with revenues of \$5.1 million (of which \$1.9 million was reimbursement for qualifying expenses under the BARDA contract for Tebipenem HBr) for the second quarter of 2021. The 2Q21 10-Q additionally reported that Spero spent \$6.4 million on research and development for Tebipenem HBr in the second quarter of 2021, and that Spero had \$99.2 million in cash, cash equivalents and marketable securities as of June 30, 2021.

September 13, 2021 H.C. Wainwright 23rd Annual Global Investment Conference

240. On September 13, 2021, Spero’s Chief Operating Officer, Christina Larkin, presented at the H.C. Wainwright 23rd Annual Global Investment Conference. During her presentation, Larkin stated that the ADAPT-PO Trial was a “landmark” and “successful” study. She further stated that “Now importantly, these results were similar across all the subgroups that we evaluated and successfully achieved the outcome of demonstrating *the tebipenem oral achieved the similar outcome to IV ertapenem.*”

241. Larkin stressed that the ADAPT-PO Trial had an “important study design” that met FDA specifications and highlighted the multi-step test required by the FDA as “the combination

of this data [clinical cure and microbiological eradication] that *measured patients' overall response and is the primary endpoint.*" Larkin further represented that Spero *"successfully met the primary endpoint in meeting this non-inferiority to compare oral tebipenem to IV ertapenem, and the FDA NI-margin was set at a negative 12.5%...and we successfully cleared that hurdle of non-inferiority."*

242. Larkin also told analysts and investors that the Company was on schedule to submit the NDA to the FDA, stating, *"We have successfully completed the single trial that's needed for U.S. approval and submitting our NDA in the fourth quarter."* She added, "Tebipenem has received Fast Track designation, which means that it will have an eight-month review once it's submitted."

243. Larkin also told analysts and investors that from the meetings Spero had with the FDA, the ADAPT-PO Trial data supported FDA approval for Tebipenem HBr, stating: "We've had a successful pre- NDA meeting with the FDA and confirm that the single trial is adequate to seek approval."

September 16, 2021 Press Release for 2021 Infectious Disease Society of America Week

244. On September 16, 2021, Spero issued a press release that provided posters intended for use at the upcoming IDSA IDWeek 2021 to be held September 29 - October 3, 2021. The press release provided a hyperlink to Spero's website that contained the posters to be used during the IDSA ID Week 2021 (the "2021 IDSA ID Week Posters"). One of the presentation posters, number 1122 titled "Effect of Aluminum Hydroxide/Magnesium Hydroxide/Simethicone and Omeprazole on the Pharmacokinetics of Tebipenem Pivoxil Hydrobromide (TBP PI-HBr) in Healthy Adult Subjects" (the "2021 IDSA Week Poster 1122"), highlighted the ADAPT-PO Trial data, stating that "A completed Phase 3 study of patients with complicated urinary tract infection or acute

pyelonephritis *found that oral TBP-PI-HBr was non-inferior to intravenous ertapenem for clinical and microbiological response.*”

245. Another of the 2021 IDSA ID Week Posters, number 1120 titled “Absorption, Metabolism, and Excretion of [14C]-Tebipenem Pivoxil Hydrobromide (TBP-PI- HBr) Following a Single Oral Dose in Healthy Male Subjects” (the “2021 IDSA Week Poster 1120”), also emphasized the ADAPT-PO Trial data, stating “Tebipenem pivoxil hydrobromide (TBP-PI-HBr) is an oral carbapenem with activity against multidrug-resistant gram-negative pathogens.”

September 22, 2021 Oppenheimer Fall Healthcare Life Sciences & Med Tech Summit

246. On September 22, 2021, Defendant Mahadevia represented Spero at the Oppenheimer Fall Healthcare Life Sciences & Med Tech Summit, where he presented on Tebipenem HBr to analysts and investors. During the prepared portion of his presentation, Defendant Mahadevia discussed the “positive” ADAPT-PO Trial results, stating that the findings *“showed that our oral medicine is as efficacious and has similar safety profile to ertapenem.”*

247. Defendant Mahadevia also stressed the FDA’s high testing requirements, stating that “patients not only have to feel better or show a clinical response, but they also have to show microbiological response.” After that, he stated, the “FDA requires patients to wait until 7 days -- 17 days to 21 days after their first dose, in order to show that not only are we get clearing the bug but you're helping the bugs stay gone... and we're pleased to say that we met that test,” “not only you have to be comparable, but that comparability [of] that data set has to be tight enough that you're above a certain difference threshold - *that difference was agreed with FDA at minus 12.5% and we passed that with flying colors,*” and “*we can say that tebipenem and ertapenem have comparable effects on this ill patient population.*”

248. Defendant Mahadevia also reiterated during the presentation that the Company is “planning for NDA submission in the fourth quarter of 2021,” and “we have fast track which comes with an eight-month review cycle should the NDA be successfully accepted.” Moreover, he assured investors and analysts that the ADAPT-PO Trial results met FDA approval standards, stating, “[W]e know from our pre-NDA discussions and multiple FDA discussions prior to that one *that this well-controlled pivotal trial will form the basis of an NDA submission.*”

249. During the Q and A portion of the presentation, an analyst asked Defendant Mahadevia to shed some light on the timeframe for the NDA. Defendant Mahadevia replied by stating Spero was anticipating the fourth quarter of 2021 for submitting the NDA and said that “we have everything we need in hand to prepare and finalize the NDA submission.”

September 29, 2021 2021 Cantor Virtual Global Healthcare Conference

250. On September 29, 2021, Defendant Mahadevia represented Spero at the 2021 Cantor Virtual Global Healthcare Conference, where he presented Tebipenem HBr to analysts and investors. During the prepared portion of his presentation, Defendant Mahadevia discussed the “pivotal” ADAPT-PO Trial, telling investors and analysts that the ADAPT-PO Trial’s results “*demonstrated that tebipenem had comparable efficacy to ertapenem.*”

251. Defendant Mahadevia also stressed the FDA’s high testing requirements, stating that “patients need to feel better as per an FDA standard questionnaire” and “need to clear the microbes in their urine above a certain threshold,” then “the FDA for their guidance has asked us to measure this response a week to 10 days after the patient has completed dosing.”

252. Defendant Mahadevia also discussed the crucial non-inferiority margin of -12.5% that the FDA mandated Tebipenem HBr meet, describing it as “one more hurdle on us in terms of showing that we have a successful trial.” He stated that “*Tebipenem cleared [the non-inferiority*

*margin] with flying colors” and he concluded, “through an extremely stringent test, **an all oral regimen of tebipenem was able to show that it could do the same thing for patients as IV ertapenem.**”*

253. Defendant Mahadevia also reiterated during the presentation that the Company is planning to file its NDA in the fourth quarter, noting “fourth quarter, we continue to expect our NDA submission.” Moreover, he assured investors and analysts that the ADAPT-PO Trial results met FDA approval standards, stating, “through our multiple interactions with FDA, including a pre-NDA meeting, we know that one well controlled pivotal trial, that’s ADAPT-PO, will perform the basis of an NDA submission” and “[w]e have what we need in hand to complete that NDA submission.”

254. He further assured investors and analysts that “we’re in a strong financial position,” “[w]e are funded into the fourth quarter of 2022, including the Pfizer transaction,” and “we’ve had an established track record of complementing equity with other sources [including] the \$57 million grant that we signed with BARDA [t]hat’s funded tebipenem and continues to help fund our investment in tebipenem.”

255. During the Q and A portion of the presentation, an analyst asked Defendant Mahadevia to give some insight into Spero’s opportunities to grow internationally. Defendant Mahadevia replied by saying the Company is focused on a “step-wise approach” stating, “[w]e are laser-focused on getting tebipenem approved in the US today.”

October 28, 2021 Press Release

256. On October 28, 2021, Spero issued a press release titled, “Spero Therapeutics Submits New Drug Application to U.S. FDA for Tebipenem HBr for the Treatment of Complicated Urinary Tract Infections including Pyelonephritis,” announcing that it had submitted Tebipenem

HBr's NDA to the FDA. Specifically, Defendant Mahadevia stated that the submission of the NDA was a major step towards the Company's goal of providing cUTI patients with oral treatment. He further noted that, if the NDA was approved, Tebipenem HBr would help patients significantly while also reducing healthcare resource utilization. The press release stated, in relevant part:

Spero [. . .] today announced the submission of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA), seeking approval for tebipenem HBr tablets for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by susceptible microorganisms. If approved, tebipenem HBr would be the only oral carbapenem antibiotic available for use in cUTI.

“With the submission of this NDA, we have taken a major step towards potentially providing a substantial number of appropriate cUTI patients with an oral treatment option that could replace historical use of intravenous (IV) therapy,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “If approved, we believe tebipenem HBr could help patients significantly, and the avoidance of IV administration could lead to reduced healthcare resource utilization. We look forward to working with the FDA during the NDA review process as we prepare for tebipenem HBr's anticipated launch in the second half of 2022.”

The NDA submission includes previously communicated positive data from the Phase 3 ADAPT-PO trial. ***This data showed that ADAPT-PO met its primary endpoint by demonstrating that oral tebipenem HBr was statistically non-inferior to IV ertapenem in the treatment of patients with cUTI and patients with acute pyelonephritis (AP).***

November 10, 2021 Press Release

257. On November 10, 2021, Spero issued a press release titled, “Spero Therapeutics Announces Third Quarter 2021 Operating Results and Provides Business Update,” announcing its operating results for the period ended September 30, 2021 (“3Q 2021”) and providing updates regarding Tebipenem HBr. Specifically, Defendant Mahadevia stated that one of the Company's accomplishments during 3Q 2021 was its NDA submission for Tebipenem HBr which, if approved, would be the first oral carbapenem antibiotic available for cUTI patients. The press release also

stated that the Company anticipated a commercial release for Tebipenem HBr in the second half of 2022, pending FDA approval. The press release stated, in relevant part:

“During the quarter, we strengthened both our leadership team and financial position, while moving tebipenem HBr closer to a point where cUTI patients may soon have a solution to their existing unmet need,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “Chief among these accomplishments was our recent NDA submission for tebipenem HBr, which, if approved, would make it the first oral carbapenem antibiotic available for use in cUTI. [”]

* * *

Clinical Highlights and Upcoming Milestones

Tebipenem HBr:

In October 2021, Spero submitted a new drug application (NDA) to the United States Food and Drug Administration (FDA), seeking approval for tebipenem HBr tablets for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by susceptible microorganisms. The NDA submission includes previously communicated positive data from *ADAPT-PO showing the Phase 3 trial met its primary endpoint by demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous (IV) ertapenem in the treatment of patients with cUTI and patients with acute pyelonephritis (AP)*. If approved, tebipenem HBr would be the only oral carbapenem antibiotic available for use in cUTI.

The Company expects a commercial launch for tebipenem HBr in the second half of 2022, subject to its approval by the FDA.

258. The press release also reported that the Company’s 3Q 2021 net loss was \$22.5 million, or \$0.70 per common share, with total revenue of \$3.1 million. For the same period one year prior, Spero’s net loss was \$18.9 million, or \$0.86 per share, with total revenue of \$4.0 million. The press release also reported that the Company had \$123.4 million in cash, cash equivalents and marketable securities as of September 30, 2021.

November 10, 2021 Earnings Call

259. On the same day, during an earnings call to discuss the Company's financial results for 3Q 2021, Defendant Mahadevia gave a presentation regarding the Company's milestones and its progress towards the launch of Tebipenem HBr. Specifically, Defendant Mahadevia stated that one of the major milestones achieved by the Company in 3Q 2021 was the submission of the NDA package to the FDA for approval of Tebipenem HBr tablets. Defendant Mahadevia continued to state that a key portion of the NDA package was the positive data set from the ADAPTO-PO Trial, which demonstrated that the oral intake of Tebipenem HBr was non-inferior to the traditional IV ertapenem treatment for cUTIs. Defendant Mahadevia also stated that the FDA had previously indicated that positive results from single well-controlled pivotal trials such as the ADAPT-PO Trial could be sufficient to support the approval of an NDA for Tebipenem HBr. Defendant Mahadevia continued by providing a timeline on estimated FDA approval, stating in relevant part:

Spero's primary focus remains on preparing for an anticipated tebipenem HBr commercial launch in the second half of 2022. And I'm pleased to say that, over the past months, we've achieved key milestones to advance our efforts towards this important goal.

Chief among these milestones was our recent submission of an NDA package, seeking approval for tebipenem HBr tablets for the treatment of complicated urinary tract infections, including pyelonephritis caused by susceptible microorganisms. A key part of this NDA package is the positive data set from our Phase III ADAPT-PO clinical trial. ***These data showed that, ADAPT-PO met its primary endpoint by demonstrating within an all-oral regimen of tebipenem HBr, was non-inferior to an all-IV regimen of ertapenem for the treatment of complicated urinary tract infection or cUTI and acute pyelonephritis or AP.***

Previous FDA interactions and written communications support our efforts to advance tebipenem HBr towards commercialization. They indicate the positive results from single well-controlled pivotal trials such as ADAPT-PO, could be sufficient to support the approval of an NDA for tebipenem HBr in the treatment of cUTI, including pyelonephritis.

Further, through a pre-NDA meeting, the FDA also previously endorsed the structure in the form of our recent NDA submission. The agency indicated that, the data set and CMC plan that are now included in the package meet FDA submission standards. Given our submission date of 27 October, we anticipate that, if FDA's

initial two-month review during this filing period is successful, the formal NDA review clock will start at the end of the year with a PDUFA date six months from that point or in mid-2022.

260. Defendant Mahadevia also emphasized the “rigorous design” of the ADAPT-PO Trial in his prepared statements, stating the following, in relevant part:

In addition to supporting our NDA submission, another key goal of the ADAPT-PO trial was to provide physicians with the confidence needed to prescribe oral tebipenem HBr to cUTI patients who would otherwise receive IV therapy. We therefore designed ADAPT-PO as the first ever head-to-head comparison of an all-oral versus an all-IV regimen in cUTI. ***Thanks to this rigorous design, we believe we have achieved our goal as data show that tebipenem HBr can provide the convenience of an oral therapy without making compromises on clinical response, safety or tolerability.***

November 10, 2021 Form 10-Q

261. On November 10, 2021, the Company filed its quarterly report with the SEC for the period ended September 30, 2021 (the “3Q21 10-Q”). The 3Q21 10-Q was signed by Defendants Mahadevia and Shukla and contained SOX certifications signed by Defendants Mahadevia and Shukla attesting to its accuracy.

262. The 3Q21 10-Q described Spero’s Tebipenem HBr as the Company’s “most advanced product candidate” that is “designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections.” In a section of the 3Q21 10-Q titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” the 3Q21 10-Q stated that the Company’s “ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates.” The 3Q21 10-Q also stated that Spero submitted the NDA to the FDA “for tebipenem HBr tablets for the treatment of complicated urinary tract infections, including pyelonephritis, caused by susceptible microorganisms.” The 3Q21 10-Q stressed that “[t]reatment with effective orally administrable antibiotics may prevent

hospitalizations for serious infections and enable earlier, more convenient and cost-effective treatment of patients after hospitalization.”

263. The 3Q21 10-Q reported a quarterly net loss of \$22.5 million, or \$0.70 per share, with revenues of \$3.1 million (of which \$721,000 was reimbursement for qualifying expenses under the BARDA contract for Tebipenem HBr) for 3Q 2021. The 3Q21 10-Q additionally reported that Spero spent \$5.7 million on research and development for Tebipenem HBr in the third quarter of 2021, and that Spero had \$123.4 million in cash, cash equivalents and marketable securities as of September 30, 2021.

November 24, 2021 Piper Sandler 33rd Annual Virtual Healthcare Conference

264. On November 24, 2021, Defendant Mahadevia represented Spero at the Piper Sandler 33rd Annual Virtual Healthcare Conference, where he discussed the ADAPT-PO Trial with analysts and investors. During the prepared portion of his presentation, Defendant Mahadevia only discussed the total patient population of the ADAPT-PO Trial, stating “we randomized a fairly large patient set, almost 1,350 patients, one to one and patients either got all oral tebipenem or all-IV ertapenem.” He characterized the ADAPT-PO Trial as a “landmark” and “pivotal” study with “positive results,” stating “***[Tebipenem HBr] passed a very tough test.***”

265. Defendant Mahadevia also stressed the FDA’s high testing requirements, stating that “we’ve set tebipenem for stringent test, all oral against all the IV. It has to meet that two-part test, feel better and clearer urine and you have to wait time after the medicine is done being dosed [7-10 days] before you can measure it.” He went on, stating, “[T]he FDA also requires that data set is fairly tight” “***so they set a non-inferiority margin where the lower bound of that confidence interval in the left hand side cannot cross minus 12.5%.***” He finished by stating, “[W]ith all of that our oral regimen compared well to ertapenem in the statistical test [a]nd ***we can say that***

tebipenem and ertapenem drive comparable outcomes in a fairly ill patient population with cUTI.”

266. Defendant Mahadevia also mentioned that Spero secured “fast track designation from FDA [a]nd if our application completes that review phase, which could take two months after our submission, we will begin a six-month review phase for the application.” Moreover, he assured investors and analysts that the ADAPT-PO Trial results met FDA approval standards, stating, “[W]e know from multiple FDA interactions as well as a pre- NDA meeting, that the ADAPT-PO trial is sufficient for the basis of an NDA submission” and “[w]e’ve made that submission.”

267. Defendant Mahadevia also told investors and analysts that Spero “signed a revenue interest financing agreement [extending] our cash runway [] into the second half of ’23 [and we’re] investing that to be able to bring tebipenem in the pipeline to market.”

268. On December 1, 2021, Defendant Mahadevia represented Spero at the 4th Annual Evercore ISI HealthCONxConference. During the Q and A portion of his presentation, an analyst asked Defendant Mahadevia if there are any issues with Tebipenem HBr and whether an FDA advisory committee would be convened for review of Tebipenem HBr. Defendant Mahadevia responded by stating the following:

And so as we look at the data set and reflect on our pre-NDA discussions and our many discussions before that, we are not asking for anything that's outside of the guidance. We are going right down the fairway both with the ADAPT-PO trial design as well as what we're asking for on the basis of it. So we wouldn't -- we can't think of a particular issue that would drive an [Advisory Committee]. We will say that sometimes the FDA uses [Advisory Committees] to showcase a particular medicine or approval pathway. We've seen that in our field. So that would be the only reason we could think of why it might happen, but not for a kind of answering a policy question this year.

269. During the Q and A portion of the presentation, another analyst asked Defendant Mahadevia about the cUTI patient population that could benefit from Tebipenem HBr. Defendant

Mahadevia answered, “[T]he patient population that we can serve with the medicine is quite large [a]nd we’ve used multiple triangulating sources of data to help us understand that [including] with ertapenem the comparator in the ADAPT-PO’s trial usage in cUTI.”

January 3, 2022 Press Release

270. On January 3, 2022, Spero issued a press release titled, “Spero Therapeutics Announces FDA Acceptance and Priority Review of New Drug Application for Tebipenem HBr for the Treatment of Complicated Urinary Tract Infections including Pyelonephritis.” The press release announced that the FDA had granted the Tebipenem HBr NDA Priority Review and Fast Track designations.² Defendant Mahadevia stated that the FDA’s acceptance of the Tebipenem HBr NDA was an important accomplishment and that the Company was committed to working with the FDA throughout the review process. The press released further stated the following, in relevant part:

Spero [. . .] today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review designation and confirmed the acceptance for substantive review of the New Drug Application (NDA) seeking approval for tebipenem HBr oral tablets for treatment in adult patients with complicated urinary tract infections (cUTI), including acute pyelonephritis, caused by susceptible microorganisms. Tebipenem HBr has been granted Qualified Infectious Disease Product (QIDP), Fast Track, and Priority Review designations for these cUTI indications. The Agency is planning to hold an Advisory Committee meeting to discuss this application and has also set a Prescription Drug User Fee Act (PDUFA) target action date of June 27, 2022.

“The FDA acceptance of this NDA is a major step forward in our mission to provide patients the first and only oral carbapenem antibiotic to treat cUTI. If approved, tebipenem HBr may provide patients an oral treatment option, allowing them to potentially either recover at home from their infections or leave the hospital sooner,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero. “This is an important accomplishment and an exciting moment for all of us at Spero, as we execute our plan on becoming a commercial organization. We are committed to

² Priority Review designation means the FDA aims to take action on the application within six months compared to the ten months under standard review, and Fast Track designation is to expedite the review of drugs used to treat serious conditions.

working closely with the FDA throughout the NDA review process and look forward to tebipenem HBr's anticipated launch in the second half of 2022."

The NDA submission includes previously communicated positive data from the Phase 3 ADAPT-PO trial. ***These data showed that ADAPT-PO met its primary endpoint by demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous (IV) ertapenem in the treatment of patients with cUTI and patients with acute pyelonephritis (AP).***

David Melnick, M.D., Chief Medical Officer of Spero, added, "ADAPT-PO was rigorously designed both to support this NDA and to provide physicians with the confidence needed to prescribe oral tebipenem HBr to appropriate patients in place of IV therapy, if approved. We believe the positive results from the trial have allowed us to accomplish this first goal and indicate that use of tebipenem HBr may ultimately improve patient care and reduce healthcare resource utilization in cUTI."

January 19, 2022 Press Release

271. On January 19, 2022, Spero issued a press release that announced the Company and BARDA had agreed to bolster their partnership to develop treatments for pediatric patients using Tebipenem HBr to fight cUTIs and pyelonephritis. The press release reported that the parties modified their 2018 contract to raise the total possible contract value to \$59.7 million, with BARDA raising its funding from \$12.9 million to \$46.9 million. In the press release, Defendant Mahadevia stressed the importance of the ADAPT-PO Trial results, stating that the modified contract ***"provides further external validation for tebipenem HBr and its robust clinical dataset."***

272. The press release also stated that the "[NDA] seeking approval for tebipenem HBr oral tablets for treatment in adult patients with cUTI, including pyelonephritis, caused by susceptible microorganisms, [is] under review by the United States Food and Drug Administration."

January 25, 2022 Form 8-K with Attached Corporate Presentation Slides

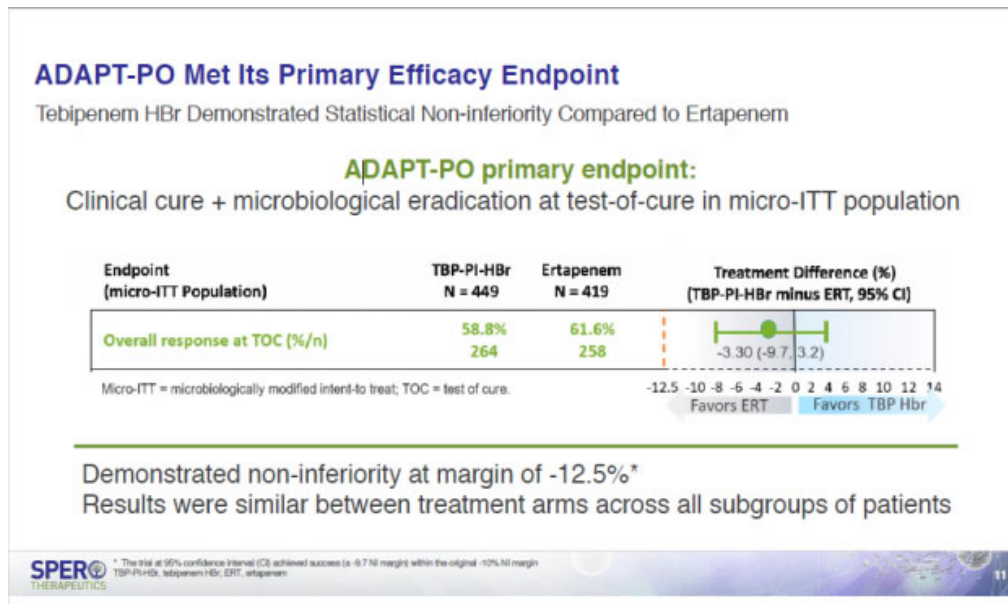
273. On January 25, 2022, Spero filed a Form 8-K with the SEC. Attached to the Form 8-K was Exhibit 99.1 which contained a slideshow titled "January 2022 Spero Therapeutics

Corporate Presentation” (the “January 2022 Slides”). The January 2022 Slides stated that the ADAPT-PO Trial was a “landmark” study that produced “Robust” results and further repeated that ***“ADAPT-PO Phase 3 met its primary endpoint in landmark trial – Oral tebipenem HBr demonstrated noninferiority to IV ertapenem in cUTI and AP, Overall combined response rate: Oral tebipenem HBr response rate of 58.8% versus 61.6% for IV ertapenem (-3.3%; -9.7, 3.2; -12.5% NI margin).”***

274. The January 2022 Slides also stated that “Tebipenem HBr, if approved as the first oral carbapenem, could allow appropriate patients the opportunity to receive treatment in the community setting.” The January 2022 Slides also touted that ***“Tebipenem HBr Demonstrated Statistical Non-inferiority Compared to Ertapenem...at margin of -12.5%”*** based on analyses of the micro-ITT population and that the “Results were similar between treatment arms across all subgroups of patients.” The January 2022 Slides stated that “ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes: Clinical cure rates at [TOC] for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms.”

275. The January 2022 Slides also referenced the NDA submission and boasted that the ADAPT-PO Trial was “One well-controlled pivotal trial to form the basis for an NDA submission as per FDA interactions,” and said that “Positive ADAPT-PO Trial Results Support an accepted NDA submission...with Priority Review, PDUFA Date: June 27, 2022.” Additionally, the January 2022 Slides addressed Spero’s financial condition, stating that “HCR Revenue Interest Funding (9/30/2021): \$50M upfront in October 2021 plus \$50M upon FDA approval of tebipenem HBr, extends cash runway into 2H 2023,” “BARDA/DTRA non-dilutive funding award for tebipenem HBr up to \$69.7M” with “additional awards and alliances provid[ing] funding for the pipeline,”

and that “Tebipenem HBr Well Positioned to Recognize Significant Market Opportunity.” The January 2022 Slides contained the following slides, in relevant part:



ADAPT-PO Key Secondary Endpoints Evaluating Patient Outcomes

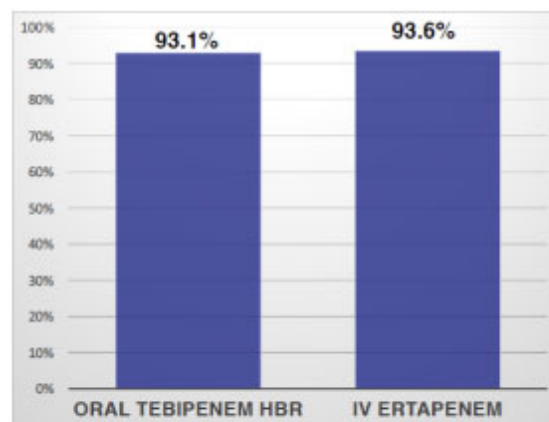
Clinical cure rate is a key determinant in routine clinical management of cUTI patients

Clinical cure rates at test-of cure (TOC) for micro-ITT groups comparable between the oral tebipenem HBr and IV ertapenem treatment arms

Durable clinical response observed with high clinical cure rates at TOC sustained through late follow-up visit

Median duration of therapy was similar for both treatment groups

Comparable Clinical Cure Rates at TOC



SPERO THERAPEUTICS Micro-ITT = Microbiological Intent-to-treat

276. The statements referenced above in ¶¶ 222-275 were materially false and misleading, and failed to disclose material facts necessary to make the statements made not false

and misleading. Specifically, the Individual Defendants willfully or recklessly made false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval; (3) Spero faced an unusually high amount of questions and inquiries from the FDA before and after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company's workforce and a shift in the Company's focus; (6) due to the foregoing, Spero's reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed to maintain adequate internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge While False and Misleading Statements Continue

March 31, 2022 Press Release

277. On March 31, 2022, Spero issued a press release titled, "Spero Therapeutics Announces Fourth Quarter and Full Year 2021 Operating Results and Provides Business Update," announcing its operating results for the 2021 Fiscal Year and updates to the FDA review process of the Tebipenem HBr NDA. Specifically, the Company announced that the FDA had notified Spero that ***the Tebipenem HBr NDA had deficiencies that would preclude discussions of labeling and post-marketing requirements***. Defendant Mahadevia stated that the Company was communicating with the FDA and focused on addressing the deficiencies. Defendant Mahadevia continued to state that, given how early in the review process the labeling discussions were

scheduled, they believed that there was still time to progress to the labeling discussions within their anticipated timeline and continued to anticipate a second-half of 2022 commercial launch for Tebipenem HBr. The press release stated, in relevant part:

The U.S. Food and Drug Administration (FDA) has notified Spero that, as part of its ongoing review of Spero's New Drug Application (NDA) for tebipenem HBr, it has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time. The FDA stated that the notification does not reflect a final decision on the information under review. Spero intends to work with the FDA to seek to resolve the deficiencies expeditiously.

The FDA previously assigned a Prescription Drug User Fee Act (PDUFA) goal action date of June 27, 2022, for completion of its review of the NDA, and initially targeted the midpoint of that review period to communicate proposed labeling and, if necessary, any post-marketing requirement and/or commitment requests to Spero. The Company noted that there are three months remaining before the PDUFA goal action date. Spero also has a late cycle review meeting scheduled with the FDA and expects to provide an update on or before its next earnings call in May 2022.

"We continue to have an active dialogue with the FDA," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero. "We are focused on doing everything we can to address the deficiencies and, given how early in the review period the labeling discussions were originally scheduled, we believe there would be sufficient time to progress to labeling discussions within the existing PDUFA timeframe. However, we do not yet know the effect of this notification, if any, on our anticipated timelines or on the ultimate approval prospects of tebipenem HBr. We continue to prepare for an anticipated commercial launch of tebipenem HBr in the second half of 2022, as we work with the FDA. If approved by the FDA, we believe tebipenem HBr may offer healthcare providers, payers and patients an important oral antibiotic alternative to IV treatment for cUTI for patients with limited oral treatment options."

278. The press release also reported that the Company's fourth quarter of 2021 net loss and 2021 Fiscal Year net loss was \$29.2 million, or \$0.90 per common share, and \$89.8 million, or \$2.91 per share, respectively. The press release further reported that the fourth quarter of 2021 generated \$2.7 million in revenue and the 2021 Fiscal Year generated \$18.3 million in total revenue. For the same period one year prior, Spero's net loss for the fourth quarter of 2020 was \$18.6 million, or \$0.68 per share, and the Company's net loss for the 2020 Fiscal Year was \$78.8

million, or \$3.52 per share. Moreover, the press release reported that the Company had \$146.4 million in cash, cash equivalents and marketable securities as of December 31, 2021.

March 31, 2022 Earnings Call

279. That same day, on March 31, 2022, Spero held an earnings call with investors and analysts to discuss the Company's fourth quarter of 2021 and 2021 Fiscal Year financial results. During the call, both Defendants Mahadevia and Shukla addressed investors and analysts. In his prepared statement, Defendant Mahadevia said Spero continues "to have an active dialogue with [the] FDA, and we'll continue to collaborate with them on the best path forward for tebipenem as quickly as we can. If this can be done to the FDA['s] satisfaction, we believe there would be sufficient [time] to progress labeling anti-PMC PMR discussions within the existing PDUFA time frame, given how early in the review period those discussions were originally scheduled to occur."

280. Defendant Mahadevia also stated in his prepared statement that the Company "continue[s] to believe in the strength of our application" and that the "***foundation of that is our previously announced data from the Phase 3 ADAPT-PO trial.***" He also stressed the success of the ADAPT-PO Trial, stating the following, in relevant part:

These data showed the trial meeting its primary endpoint as specified in the protocol by demonstrating that oral tebipenem HBr was statistically noninferior to intravenous tebipenem in the treatment of patients with complicated urinary tract infections or cUTI, and patients with acute pyelonephritis or AP.

We are expecting the publication of the ADAPT-PO trial results in a high-impact peer review journal in early Q2. ADAPT-PO was designed as the first head-to-head comparison of an oral versus IV regimen in cUTI. We believe it shows that tebipenem can provide the benefits of an oral therapy without making any compromises on clinical response, safety or tolerability. We believe data from the trial not only supports our NDA, but if approved by the FDA, will potentially provide physicians with the confidence needed to prescribe oral tebipenem HBr to appropriate patients in the place of IV therapy.

281. During the Q and A portion of the earnings call, an analyst asked Defendant Mahadevia about how Spero was communicating with the FDA regarding the identified deficiencies in the Tebipenem HBr NDA. Defendant Mahadevia responded by saying that Spero continues “to have a frequent and active interaction with our colleagues at the FDA” and continues “to engage with them on a variety of subjects within the NDA application as the process has gone on.” After the analyst asked a follow up question, Defendant Mahadevia stated that Spero has “engagement with the agency on a variety of topics” and had “engaged with them real time.” After the analyst asked another follow up question, Defendant Mahadevia stated that Defendants “had a very productive and collaborative engagement with [the] FDA, where we continue to correspond with them on the basis of the data that we’ve submitted.” Later in the earnings call, an analyst asked the following question: “So first question is what typically occurs during a late-cycle review just generally? And then is that where at some point? And how would that shift in terms of where your discussions are with the FDA?” Defendant Mahadevia responded:

I think one point that you're alluding to is that our PDUFA date is in late June, and we're sitting here in late March. We are about halfway through the planned review period. And you make an important point that that late cycle review meeting is another opportunity for us to engage with the agency on the topics that we've continued to be engaging with them on during the review period.

So what I want to emphasize from our prior remarks is that we are in a deliberative and collaborative phase with our colleagues and agencies, not in a decisional phase and that continued dialogue including the late cycle visit gives us an opportunity to continue to work with them collaboratively to find the right path forward.

March 31, 2022 Form 10-K

282. On March 31, 2022, Spero filed its annual report for the 2021 Fiscal Year on Form 10-K with the SEC (the “2021 10-K”). The 2021 10-K was signed by Defendants Mahadevia,

Shukla, Deshpande, Jackson, Pottage, Smith, Thomas, and Vink and contained SOX certifications signed by Defendants Mahadevia and Shukla attesting to its accuracy.

283. The 2021 10-K described Tebipenem HBr as the Company's "most advanced product candidate" that has multiple "key attributes" that "support our confidence in tebipenem HBr's commercial potential." In a section of the 2021 10-K titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," the 2021 10-K stated that the Company's "ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates." The 2021 10-K also stated that "tebipenem HBr, if successfully developed and approved, would have a meaningful patient impact and significant commercial applications for the treatment of certain bacterial infections that cause cUTI in both the community and hospital settings" and that, "[i]n addition to cUTI, ... tebipenem HBr has the potential to treat other serious and life-threatening infections."

284. The 2021 10-K also stated that, regarding the safety and efficacy of Tebipenem HBr, the drug candidate has "the potential to be a safe and effective treatment for cUTI," given the *"positive topline data results from ADAPT-PO, the pivotal Phase 3 clinical trial evaluating ... tebipenem HBr"* which *"achieved its primary objective, as specified in the protocol, demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous ertapenem in the treatment of patients with cUTI and patients with AP with respect to the primary endpoint of overall response at the test-of-cure ('TOC') visit in the microbiological-intent-to-treat ('ITT') ('micro-ITT') population."*

285. The 2021 10-K also stated that Spero intends "to work with the FDA to seek to resolve the deficiencies expeditiously." Defendants continued that "[i]f this can be done to the

satisfaction of the FDA, we believe there would be sufficient time to progress to labeling discussions within the existing PDUFA timeframe, given how early in the review period those discussions were originally scheduled to occur.” The 2021 10-K further stated that Spero continues “to prepare for an anticipated commercial launch of tebipenem HBr in the second half of 2022, as we work with the FDA.”

286. The 2021 10-K reported 2021 Fiscal Year net loss of \$89.8 million, or \$2.91 per share, with \$18.3 million in total revenue. For the same period one year prior, the Company’s net loss for the 2020 Fiscal Year was \$78.3 million, or \$3.52 per share. Of the \$18.3 million in total revenue for the 2021 Fiscal Year, \$9.9 million consisted of reimbursement from qualifying expenses under the BARDA contract for Tebipenem HBr. The 2021 10-K additionally reported that Spero spent \$28.9 million on research and development for Tebipenem HBr in the 2021 Fiscal Year. The 2021 10-K further reported that the Company had \$146.4 million in cash, cash equivalents and marketable securities as of December 31, 2021.

287. On this news, the price of Spero’s common stock fell \$1.59 per share, or 18.27%, from closing at \$8.70 per share on March 31, 2022, to close at \$7.11 per share on April 1, 2022.

April 6, 2022 Press Release

288. On April 6, 2022, Spero issued a press release that announced the publication of the ADAPT-PO Trial results in *The New England Journal of Medicine*. The press release described the ADAPT-PO Trial as a “landmark” study involving “the first Phase 3 head-to-head comparison of an all-oral versus all-IV treatment regimen in cUTI or acute pyelonephritis.” The press release also stated that Spero “seeks approval for tebipenem HBr for the treatment of cUTI, including pyelonephritis, caused by certain microorganisms, in adult patients who have limited oral treatment options” and “included the results from the completed Phase 3 trial in the NDA filed

with the FDA.” The press release also asserted that Tebipenem HBr was on schedule for potential FDA approval, stating, “[T]he FDA accepted the NDA for substantive review, granted Priority Review designation, and the FDA has assigned a PDUFA target date of June 27, 2022.”

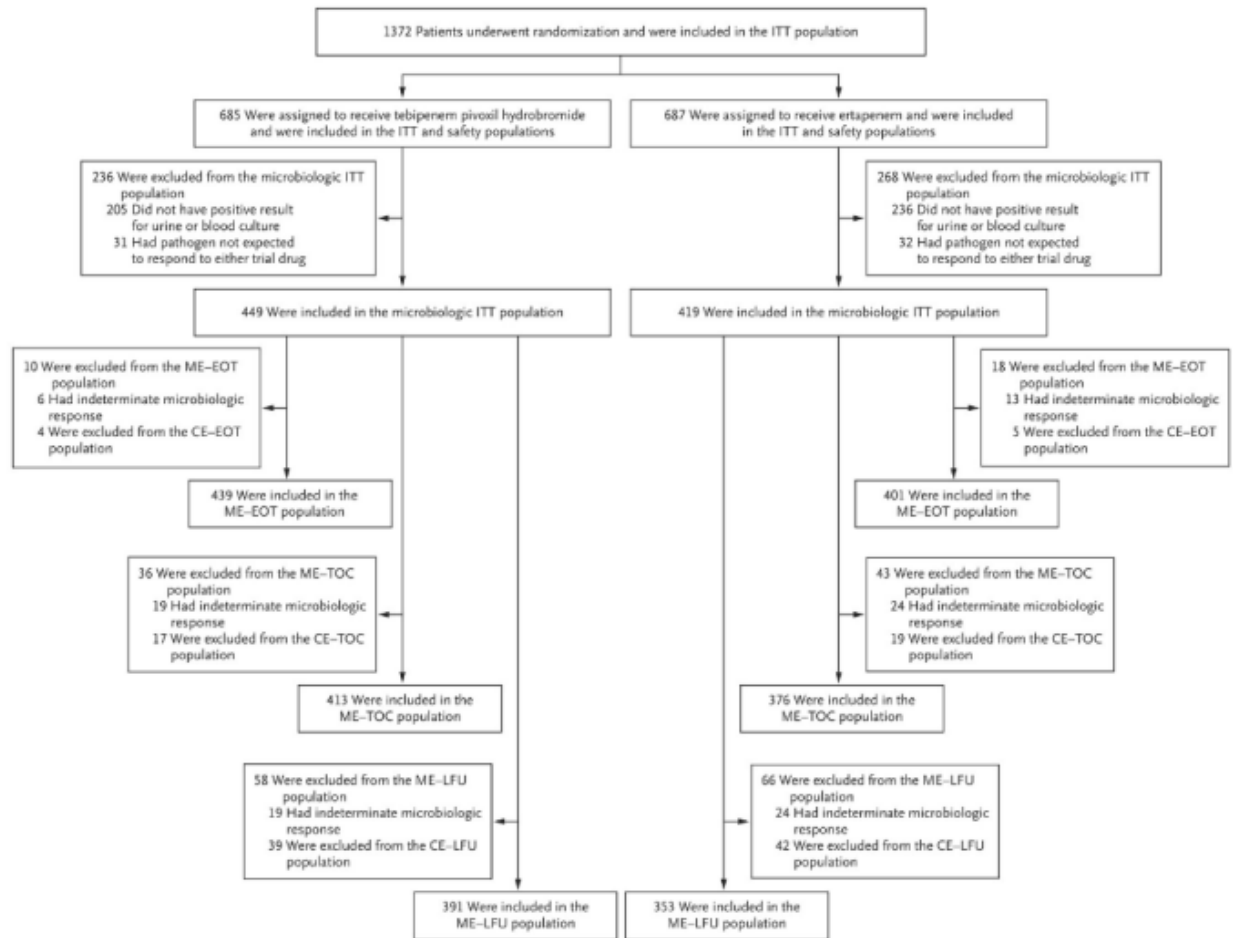
April 7, 2022 The New England Journal of Medicine Paper

289. On April 7, 2022, *The New England Journal of Medicine* published a paper titled, “Oral Tebipenem Pivoxil Hydrobromide in Complicated Urinary Tract Infection.” The paper stated that Tebipenem HBr is “an orally bioavailable carbapenem with activity against” “multi-drug resistant gram-negative pathogens” (including cUTIs and acute pyelonephritis). The paper discussed the patient population of the ADAPT-PO Trial, stating “The intention-to-treat population included all the patients who underwent randomization” and had “confirmed diagnosis of complicated urinary tract infection or acute pyelonephritis and a positive urine culture at baseline” while the “safety population included all the patients who received at least one dose of a trial drug.” The paper stated that the “microbiologically evaluable population [comprised] patients who were included in both the microbiologic intention-to-treat population and the clinically evaluable population.”

290. Regarding patient population and reaching the noninferiority margin, the paper stated that “we calculated that enrollment of approximately 1200 patients up to a maximum of 1450 (contingent on the number of evaluable patients to be included in the primary analysis population) would provide the trial with at least 90% power for the assessment of the primary end point within a noninferiority margin of 10%[, but] ***[t]he data review committee recommended enrollment up to the protocol-allowed maximum of 1450 patients [and Spero], in consultation with the FDA, revised the noninferiority margin to 12.5%.***”

291. The paper repeated some of the same data as that contained in the 2020 IDSA ID Week Slides, such as the 65.9% response for Enterobacterales in ertapenem. However, the paper and the 2020 IDSA ID Week Slides also had key disparities. For instance, the paper and the 2020 IDSA ID Week Slides differed on the response at test-of-cure for Enterobacterales for Tebipenem HBr. The paper reported 59.7% response for Tebipenem HBr, which was significantly different than the 63.0% response reported in the 2020 IDSA ID Week Slides. However, the paper's overall conclusion was the same as the 2020 IDSA ID Week Slides: "*Oral tebipenem pivoxil hydrobromide was noninferior to intravenous ertapenem with respect to the primary end point of overall response at the test-of-cure visit (58.8% and 61.6% of the patients, respectively; weighted difference, -3.3 percentage points; 95% confidence interval [CI], -9.7 to 3.2).*" The paper also stated that "Results were consistent across trial populations and subpopulations, infection types, and causative uropathogens."

292. The following flowchart contained in the paper describes the patient population in the ADAPT-PO Trial:



293. The following chart contained in the paper shows the disparity between the microbiological responses between Tebipenem HBr and IV ertapenem. The percentage 59.7% is significantly lower than the 63.0% percentage publicly disclosed in the 2020 IDSA ID Week Slides:

Table S7. By-pathogen clinical and microbiological response at test-of-cure (microbiological intent-to-treat population)

Baseline Pathogen*	Clinical Responses		Microbiological Responses	
	TBP-PI-HBr n/N (%)	Ertapenem n/N (%)	TBP-PI-HBr n/N1 (%)	Ertapenem n/N1 (%)
Overall	418/449 (93.1)	392/419 (91.6)	306/493 (62.1)	296/455 (65.1)
Enterobacterales	368/397 (92.7)	363/386 (94.0)	249/417 (59.7)	265/402 (65.9)
<i>Escherichia coli</i>	270/287 (94.1)	260/270 (96.3)	180/287 (62.7)	176/270 (65.2)
<i>Klebsiella pneumoniae</i>	46/53 (86.8)	64/71 (90.1)	24/53 (45.3)	45/71 (63.4)
<i>Proteus mirabilis</i>	32/35 (91.4)	21/23 (91.3)	17/35 (48.6)	16/23 (69.6)
<i>Enterobacter cloacae</i>	10/11 (90.9)	7/8 (87.5)	6/11 (54.5)	4/8 (50.0)
Gram-positive	71/76 (93.4)	44/51 (86.3)	57/76 (75.0)	31/53 (58.5)
<i>Enterococcus faecalis</i>	53/58 (91.4)	33/36 (91.7)	39/58 (67.2)	20/36 (55.6)
<i>Enterococcus faecium</i>	5/5 (100)	2/2 (100)	5/5 (100)	2/2 (100)
<i>Staphylococcus aureus</i>	5/5 (100)	7/8 (87.5)	5/5 (100)	3/8 (37.5)
<i>Staphylococcus saprophyticus</i>	4/4 (100)	3/6 (50.0)	4/4 (100)	5/6 (83.3)
Enterobacterales resistance phenotype†				
ESBL-positive	92/105 (87.6)	81/85 (95.3)	58/106 (54.7)	53/86 (61.6)
Fluoroquinolone-non-susceptible	143/159 (89.9)	137/146 (93.8)	89/165 (53.9)	91/149 (61.1)
Trimethoprim-sulfamethoxazole-resistant	155/168 (92.3)	160/168 (95.2)	99/172 (57.6)	109/170 (64.1)

ESBL, extended spectrum β -lactamase; FQ, fluoroquinolone; MIC = minimum inhibitory concentration; TBP-PI-HBr, tebipenem pivoxil hydrobromide; TMP-SMX, trimethoprim-sulfamethoxazole; TOC, Test-of-Cure; N= number of patients with a given pathogen; N1=total number of isolates; A patient could have more than 1 pathogen. Multiple isolates of the same species/category from the same patient were counted only once based on the isolate with the highest MIC to study drug.

* Only pathogens with at least 5 isolates in either treatment group are included.

† Resistance phenotypes defined as ESBL-positive = ceftazidime MIC ≥ 2 μ g/mL (or ceftriaxone MIC ≥ 2 μ g/mL if ceftazidime susceptibility was not available); FQ-non-susceptible = levofloxacin MIC ≥ 1 μ g/mL; TMP/SMX-resistant = TMP/SMX MIC $\geq 4/76$ μ g/mL; pathogens may be included in more than one resistance category.

294. The following chart presents the conclusions of the ADAPT-PO Trial; namely, Tebipenem HBr is noninferior to IV ertapenem:

Table 2. Primary and Secondary Efficacy End Points (Microbiologic Intention-to-Treat Population).

End Point	Tebipenem Pivoxil Hydrobromide (N = 449) number (percent)	Ertapenem (N = 419)	Treatment Difference (95% CI)* percentage points
Primary end point			
Overall response at test-of-cure visit†	264 (58.8)	258 (61.6)	-3.3 (-9.7 to 3.2)
Secondary end points			
Overall response at end-of-treatment visit†	437 (97.3)	396 (94.5)	2.8 (0.1 to 5.7)
Clinical response‡			
Clinical improvement at day 5	336 (74.8)	321 (76.6)	-1.9 (-7.6 to 3.8)
Clinical cure at end-of-treatment visit	446 (99.3)	410 (97.9)	1.4 (-0.1 to 3.4)
Clinical cure at test-of-cure visit	418 (93.1)	392 (93.6)	-0.6 (-4.0 to 2.8)
Sustained clinical cure at late follow-up	398 (88.6)	377 (90.0)	-1.5 (-5.7 to 2.6)
Microbiologic response§			
Response at day 5	427 (95.1)	397 (94.7)	0.3 (-2.7 to 3.4)
Response at end-of-treatment visit	439 (97.8)	403 (96.2)	1.5 (-0.8 to 4.1)
Response at test-of-cure visit	267 (59.5)	266 (63.5)	-4.5 (-10.8 to 1.9)
Sustained response at late follow-up	257 (57.2)	244 (58.2)	-1.5 (-7.9 to 5.0)

* Confidence intervals were calculated with the use of the method of Miettinen and Nurminen and the Cochran–Mantel–Haenszel test, with differences between the two trial groups summarized as weighted differences (stratified according to age at informed consent and diagnosis at baseline). Confidence intervals for secondary end points were not adjusted for multiplicity and were used to demonstrate consistency of the treatment effect with the primary end point; they cannot be used to infer effects.

† Overall response was defined as a composite of clinical cure and microbiologic response (see below) at the test-of-cure visit (on day 19, within a ± 2 -day window).

‡ Clinical improvement at day 5 was defined as improvement by at least one grade in at least one baseline sign or symptom of complicated urinary tract infection or acute pyelonephritis and no worsening of any baseline signs or symptoms and no new signs or symptoms of either infection that resulted in the initiation of a nontrial antibacterial therapy. Clinical cure was defined as a complete resolution or reduction of signs and symptoms of complicated urinary tract infection or acute pyelonephritis that were present at baseline and no new symptoms such that no further antimicrobial therapy was warranted. Late follow-up occurred at 25 days, within a ± 2 -day window.

§ Microbiologic response was defined as a reduction in the baseline uropathogen to less than 10^3 colony-forming units per milliliter and a negative repeated blood culture if the blood culture was positive for a uropathogen at baseline.

April 7, 2022 Society of Hospital Medicine Converge Conference

295. On or around April 7, 2022, Spero gave a presentation at the Society of Hospital Medicine (“SHM”) Converge Conference. At the SHM Converge Conference, Spero unveiled a poster titled “*Oral Tebipenem Pivoxil is Non-Inferior to IV Ertapenem in Complicated Urinary Tract Infection (cUTI) and Acute Pyelonephritis (AP): ADAPT-PO Study*” (the “2022 SHM Converge Conference Non-Inferior Poster”). The 2022 SHM Converge Conference Non-Inferior

Poster contained the micro-ITT population and provided breakdown percentages of gram-negative and gram-positive patients in the ADAPT-PO Trial. The 2022 SHM Converge Conference Non-Inferior Poster concluded that “*the primary objective was met: tebipenem pivoxil hydrobromide (600mg PO q8h) was non-inferior to ertapenem (1g IV q24h)*” and “Overall response rates at TOC were similar between treatment groups (approximately 59% in the TBP-PI-HBr group vs. 62% in the ertapenem group) and were high and similar between treatment groups at EOT (>94% in both groups).”

296. The 2022 SHM Converge Conference Non-Inferior Poster also reiterated that the NDA could still receive FDA approval, stating that, “In January 2021, the FDA granted Priority Review designation and confirmed the acceptance for substantive review of the New Drug Application (NDA) and [t]he FDA has a set a PDUFA target action date of June 27, 2022.” The 2022 SHM Converge Conference Non-Inferior Poster presented the following:

Figure 3. ADAPT-PO Analysis Populations

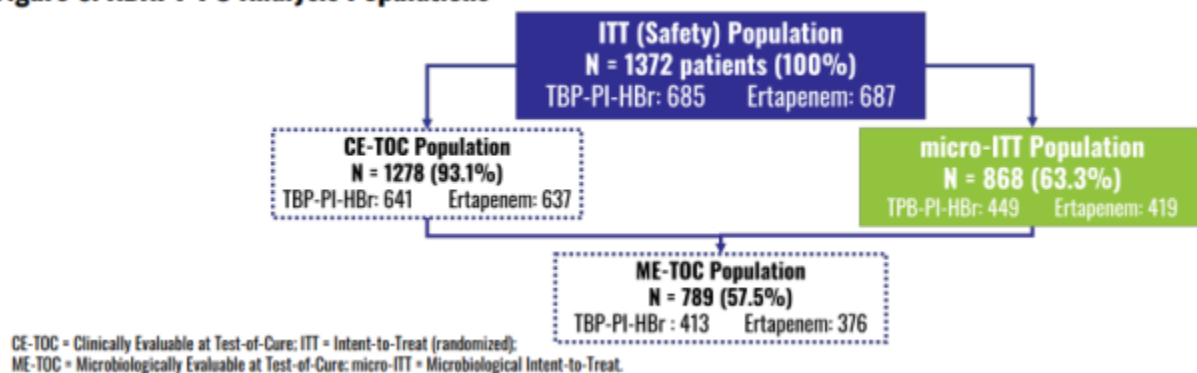


Table 2. Uropathogens isolated from urine and/or blood at baseline (micro-ITT)

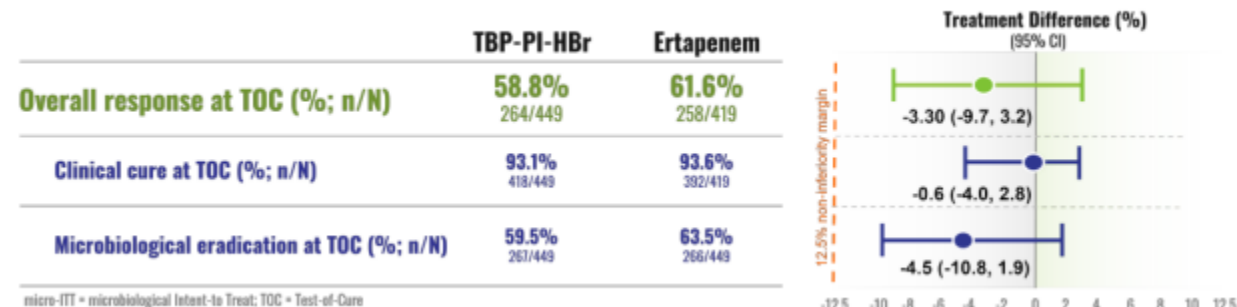
Baseline Pathogen [†]	TBP-PI-HBR (N=449)	Ertapenem (N=419)	Total (N=868)
Enterobacterales	397 (88.4%)	386 (92.1%)	783 (90.2%)
<i>Escherichia coli</i>	287 (63.9%)	270 (64.4%)	557 (64.2%)
<i>Klebsiella pneumoniae</i>	53 (11.8%)	71 (16.9%)	124 (14.3%)
<i>Proteus mirabilis</i>	35 (7.8%)	23 (5.5%)	58 (6.7%)
<i>Enterobacter cloacae</i>	11 (2.4%)	8 (1.9%)	19 (2.2%)
<i>Citrobacter freundii</i>	4 (0.9%)	3 (0.7%)	7 (0.8%)
<i>Citrobacter koseri</i>	3 (0.7%)	4 (1.0%)	7 (0.8%)
<i>Klebsiella oxytoca</i>	4 (0.9%)	3 (0.7%)	7 (0.8%)
<i>Providencia rettgeri</i>	4 (0.9%)	3 (0.7%)	7 (0.8%)
<i>Klebsiella variicola</i>	2 (0.4%)	4 (1.0%)	6 (0.7%)
<i>Serratia marcescens</i>	4 (0.9%)	2 (0.5%)	6 (0.7%)
<i>Morganella morganii</i>	4 (0.9%)	1 (0.2%)	5 (0.6%)
Gram-positive cocci	76 (16.9%)	51 (12.2%)	127 (14.6%)
<i>Enterococcus faecalis</i>	58 (12.9%)	36 (8.6%)	94 (10.8%)
<i>Staphylococcus aureus</i>	5 (1.1%)	8 (1.9%)	13 (1.5%)
<i>S. saprophyticus</i>	4 (0.9%)	6 (1.4%)	10 (1.2%)
<i>Enterococcus faecium</i>	5 (1.1%)	2 (0.5%)	7 (0.8%)

Table 3. Per-patient baseline Enterobacterales pathogen resistance phenotypes

Enterobacterales Resistance phenotype [†]	TBP-PI-HBR	Ertapenem
ESBL+	26.5%	22.0%
FQ-non-susceptible	40.2%	37.8%
TMP-SMX-resistant	42.4%	43.5%

[†] Per CLSI screening criteria: ESBL+ = ceftazidime MIC ≥ 2 μ g/mL; fluoroquinolone (FQ)-non-susceptible = levofloxacin MIC ≥ 1 μ g/mL; trimethoprim-sulfamethoxazole (TMP/SMX)-resistant = TMP-SMX MIC $\geq 4/76$ μ g/mL.

- The TBP-PI-HBr and ertapenem groups were well-matched in age and sex. Approximately 44% of patients were age ≥ 65 . (**Table 1**)
- 90% of patients in the micro-ITT were infected with Enterobacterales. (**Table 2**)
- Infections caused by resistant Enterobacterales strains were common. (**Table 3**)

Figure 5. Primary and secondary efficacy endpoints at Test-of-Cure visit (micro-ITT population).

297. Spero unveiled another poster during the 2022 SHM Converge Conference titled “Clinical Stability Indicators Between Ertapenem and Tebipenem Pivoxil, and Oral Carbapenem, in Hospitalized Adults With Complicated Urinary Tract Infection” (the “2022 SHM Conference Clinical Stability Poster”). The 2022 SHM Conference Clinical Stability Poster stated that the ADAPT-PTO Trial “*demonstrated the non-inferiority of oral tebipenem HBr versus IV ertapenem in patients with cUTI/AP.*”

April 11, 2022 Bioequivalence Article

298. On April 11, 2022, the Company published an article titled “Bioequivalence of Two Oral Formulations of Tebipenem Pivoxil Hydrobromide in Healthy Subjects” (the “April 11, 2022 Bioequivalence Article”) in *Clinical and Translational Science* and on Spero’s website. The April

11, 2022 Bioequivalence Article stated that the ADAPT-PO Trial determined that Tebipenem HBr was statistically non-inferior to IV ertapenem in patients suffering from cUTIs. The April 11, 2022 Bioequivalence Article also stated that oral tablets of Tebipenem HBr were bioequivalent to IV ertapenem, stating that “[tebipenem HBr] prodrug was developed as the first oral carbapenem for treatment of serious bacterial infections due to gram-positive and gram-negative bacteria, including drug-resistant pathogens.” It also stated that “***results of this study demonstrated that the clinical and registration formulations of [Tebipenem HBr] were [bioequivalent].***”

April 14, 2022 Pharmacokinetics Article

299. Three days later, on April 14, 2022, the Company published another article, titled “Pharmacokinetics of Oral Tebipenem Pivoxil Hydrobromide in Subjects with Varying Degrees of Renal Impairment” (the “April 14, 2022 Pharmacokinetics Article”) in *American Society for Microbiology* and on Spero’s website. The April 14, 2022 Pharmacokinetics Article reported the findings of a study focusing on Tebipenem HBr and patients with different renal function levels. The April 14, 2022 Pharmacokinetics Article also stated that “[Tebipenem HBr] is an oral carbapenem prodrug antimicrobial agent with broad-spectrum activity that includes multidrug-resistant [MDR] Enterobacterales” (gram-negative pathogens). It further stated, “[tebipenem HBr] has the potential to address an important unmet need for a new oral therapy effective in the treatment of serious bacterial infections due to MDR Gram-negative pathogens.”

April 21, 2022 ECCMID Press Release and Accompanying Presentation Posters

300. On April 21, 2022, Spero issued a press release that announced the Company would present at the 32nd European Congress of Clinical Microbiology and Infectious Diseases (“ECCMID”) meeting to be held on April 23-25, 2022. The press release contained a hyperlink to numerous slides and posters to be used during the ECCMID presentation.

301. One of the posters to be presented, titled “Efficacy of Tebipenem Pivoxil Hydrobromide in Patients with Complicated Urinary Tract Infection and/or Acute Pyelonephritis and Associated Bacteremia in ADAPT-PO” (“2022 ECCMID Poster 0213”), provided an analysis of the ADAPT-PO Trial, specifically discussing the breakdown of gram-positive and gram-negative patient results, stating the following:

· ***Oral TBP-PI-HBr was non-inferior to IV ertapenem in patients with cUTI/AP in the ADAPT-PO trial.***

· The results from this secondary analysis found that clinical and microbiological outcomes for patients with bacteremia ***were comparable for those treated with oral TBP-PI-HBr and those treated with IV ertapenem.***

· These results support the use of TBP-PI-HBr across a spectrum of patients with cUTI/AP including those with more a [sic] severe disease based on the presence of baseline bacteremia.

302. The press release also included a link that contained Abstract #01140, which was presented on April 24, 2022 and titled “Plasma Pharmacokinetics and Intrapulmonary Penetration of Tebipenem in Healthy Subjects” (the “2022 ECCMID Abstract 01140”). The 2022 ECCMID Abstract 01140 discussed the ADAPT-PO Trial results that were published in the April 7, 2022 edition of the *New England Journal of Medicine*, stating that the ADAPT-PO Trial ***“has demonstrated that oral tebipenem pivoxil hydrobromide was non-inferior to intravenous ertapenem for treating patients with complicated urinary tract infections, including acute pyelonephritis.”***

303. The press release also contained another link that contained another poster, which was presented on April 24, 2022 and titled “Tebipenem Pivoxil Hydrobromide: Safety and Tolerability Profile of the First Oral Carbapenem for Complicated Urinary Tract Infection and Acute Pyelonephritis” (the “2022 ECCMID Poster 0220”). The 2022 ECCMID Poster 0220 discussed the safety and tolerability of Tebipenem HBr in the “Pivotal” ADAPT-PO Trial, stating

that “[i]f approved, TBP-PI-HBr may provide an oral treatment option for patients with serious bacterial infections, including cUTI/AP with a safety /tolerability consistent with the carbapenem class.”

May 2, 2022 Hydrolysis Article

304. On May 2, 2022, the Company published an article titled “Evaluation of Tebipenem Hydrolysis by β -Lactamases Prevalent in Complicated Urinary Tract Infections” (the “May 2, 2022 Hydrolysis Article”) in *Antimicrobial Agents Chemotherapy* and on Spero’s website. The May 2, 2022 Hydrolysis Article discussed Tebipenem HBr’s stability to hydrolysis in organisms that cause cUTIs. The May 2, 2022 Hydrolysis Article stated that the “the β -lactamase stability data of tebipenem together with in vitro antimicrobial activity of tebipenem and pharmacokinetics/pharmacodynamics (PK-PD) of TBI-PI-HBR support the development of TBP-PI-HBR as an oral drug to treat adult cUTI/AP.”

305. The statements referenced above in ¶¶ 277-304 were materially false and misleading and failed to disclose material facts necessary to make the statements made not false and misleading. Specifically, the Individual Defendants willfully or recklessly made false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval; (3) Spero faced an unusually high amount of questions and inquiries from the FDA before and after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company’s workforce and a shift in the

Company's focus; (6) due to the foregoing, Spero's reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed to maintain adequate internal controls. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

The Truth Fully Emerges

306. On May 3, 2022, Spero issued a press release titled, "Spero Therapeutics Announces New Strategic Direction Focusing on Advancing Promising Clinical-Stage Pipeline," announcing that it would be deferring commercialization activities for Tebipenem HBr following the FDA's identification of substantive review issues relating to the Tebipenem HBr NDA. The press release also announced that *Spero would be restricting its operations and reducing its workforce by approximately 75%*. Defendant Mahadevia stated that the Company had made a strategic decision to transition its focus and resources to supporting the clinical development of its promising clinical-stage pipeline and would restructure its business to appropriately staff its new focus going forward. Defendant Mahadevia also stated that Spero would continue to engage with the FDA about making progress with Tebipenem HBr but would refrain from investments in near-term commercialization activities intended for the commercial release of Tebipenem HBr. The press release further stated, in relevant part:

Spero [. . .] today announced that *it will immediately defer current commercialization activities for tebipenem HBr* based on feedback from a recent Late Cycle Meeting (LCM) with the U.S. Food and Drug Administration (FDA) regarding Spero's New Drug Application (NDA) for tebipenem HBr. Although the review is still ongoing and the FDA has not yet made any final determination regarding approvability, the *discussion suggested that the data package may be insufficient to support approval during this review cycle*, as described below.

In connection with this development, *Spero announced that it is undertaking a reduction in its workforce by approximately 75% and a restructuring of its operations to reduce operating costs and reallocate resources* towards the clinical development programs of SPR720 and SPR206, while continuing engagement with

the FDA on the appropriate path forward for tebipenem HBr. Based on the anticipated cost-savings of this restructuring and other assumptions, Spero anticipates it will be able to fund its planned operating expenses and capital expenditure requirements pursuant to the priorities of its strategic refocusing through late 2023.

“We are disappointed that the FDA has identified substantive review issues, and we strongly believe that tebipenem HBr would offer healthcare providers, payers and patients an important oral antibiotic alternative to IV treatment for cUTI for patients with limited oral treatment options,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “After careful consideration, and in light of the current FDA position, we have made the strategic decision to transition Spero’s focus and resources to supporting the clinical development of our promising clinical-stage pipeline, including SPR720, aimed at treating nontuberculous mycobacterial lung disease, and SPR206, aimed at treating MDR gramnegative bacterial infections. Further, we will continue to engage with the FDA on the appropriate path forward for tebipenem HBr. As a result, Spero will immediately refrain from investment in near-term commercialization activities for tebipenem HBr, and instead we will restructure our business to appropriately staff our new focus going forward. We believe these actions will help preserve the ongoing viability of tebipenem HBr’s development program, enabling either eventual commercialization by Spero, or commercialization through potential partnership or other opportunities.”

Dr. Mahadevia continued, “While this decision was difficult, we believe it is in the best interest of the company and its shareholders. The need for antibiotic resistance solutions is more pressing than ever before, and both SPR720 and SPR206 are in clinical development stages and have shown promising results to date. SPR720’s Phase 2 clinical hold was recently lifted, enabling its continued development as an oral therapy for non-tuberculosis mycobacterial infection, a debilitating, chronic disease. We are also very pleased with the ongoing development of SPR206 as a treatment for MDR gram-negative lung infections. Finally, we believe in the longterm potential of tebipenem HBr for patients with cUTI and look forward to engaging the FDA on the best path forward to approval.”

“Spero is powered by incredibly hard-working and dedicated professionals who have made significant strides over the past year to bring the medicines in our pipeline forward and closer to patients. I would like to offer my heartfelt thanks to all our employees, especially those affected by today’s announcement, for their contributions to Spero. We are committed to treating all impacted team members with fairness and respect, consistent with our culture, and to supporting them through this transition,” concluded Dr. Mahadevia.

Tebipenem HBr has been granted Qualified Infectious Disease Product (QIDP), Fast Track and Priority Review designations for treatment of complicated urinary tract infection (cUTI), including acute pyelonephritis. The FDA set a Prescription

Drug User Fee Act (PDUFA) target action date for June 27, 2022. On March 31, 2022, Spero announced that as part of the FDA's ongoing review of Spero's NDA for tebipenem HBr, the FDA had identified deficiencies that precluded the discussion of labeling and post-marketing requirements/commitments at such time. Spero's LCM with the FDA was in late April 2022.

In evaluating the efficacy of tebipenem HBr in the Phase 3 (ADAPT-PO) cUTI study, the FDA conducted a separate analysis of the microbiological intent-to-treat (micro-ITT) population, relative to the prespecified analysis as set forth in the previously submitted and reviewed protocol and statistical analysis plan for ADAPT-PO. The effect of this new analysis was to reduce the number of evaluable patients in the primary analysis population compared with those resulting from the trial's pre-specified micro-ITT population as outlined in the statistical analysis plan. As a result, the FDA considers that the pre-specified non-inferiority (NI) margin of -12.5% was not met. Spero is continuing its dialogue with the FDA, as the company seeks a pathway forward for potential approval of tebipenem HBr.

307. On this news, Spero's stock price cratered, falling \$3.24 per share, or 63.65%, from closing at \$5.09 per share on May 2, 2022 to close at \$1.85 per share on May 3, 2022.

308. Analysts and investors reacted in shock to the news. On May 3, 2022, Oppenheimer issued an analyst report that stated the FDA removed approximately 15% of the patients from the ADAPT-PO Trial, of which suffered from the gram-positive bacteria *Enterococcus*, which generally causes between 10% to 15% of cUTIs. Because of this reduction in patient population in the ADAPT-PO Trial, the number of evaluable patients in the study dropped from 868 to 734, thereby causing the non-inferiority margin to rise above the required limit of -12.5%. On this news, Oppenheimer downgraded its rating of Spero stock and chose not to set a price target, stating that the "FDA's exclusion of *Enterococcus* species was a surprise to us."

309. Similarly, Berenberg Capital Markets and Cowen characterized Spero's May 2, 2022 disclosures as "disappointing." That same day, an Evercore analyst called the disclosures "shocking," stating that "*the series of events with [Spero] have rattled my (and investors') confidence and* with finite resources and early stage anti-infectives, *it's no longer a name we can*

recommend owning.” The Evercore analyst further stated that “it’s hard to know exactly what the agency is thinking.”

The Individual Defendants’ Knowledge of the Misconduct

310. The Individual Defendants knew, or were reckless in not knowing, that Spero’s ADAPT-PO Trial suffered from “deficiencies that preclude discussion of labeling and post-marketing requirements / commitments” with the FDA and that the ADAPT-PO Trial’s “data package may be insufficient to support [FDA] approval.” Further, the Individual Defendants knew, or were reckless in not knowing, that the gram-positive patients in the ADAPT-PO Trial could be excluded from consideration by the FDA, and because of their exclusion from the evaluable patient population, would prevent the ADAPT-PO Trial from meeting the mandated -12.5% non-inferiority margin between Tebipenem HBr and IV ertapenem.

311. The Individual Defendants were personally financially motivated to keep Spero’s common stock price per share as high as possible throughout the Relevant Period, as their compensation was partially entwined with the Company’s stock price. Certain of the Individual Defendants’ compensation significantly increased during the Relevant Period as well. For instance, Defendant Mahadevia’s 2021 compensation, when compared to his 2020 compensation, jumped \$80,000. In other words, Defendant Mahadevia made 14.8% more in 2021 than 2020. Interestingly, his compensation only increased by \$35,000 from 2018 to 2019 and by \$40,000 from 2019 to 2020. Similarly, Defendant Shukla, who began as CFO in January 2021, benefitted from a \$35,000 raise in July 2021, just mere months after joining Spero.

312. Making matters worse, the Individual Defendants consciously chose to conduct the ADAPT-PO Trial during the onset of the COVID-19 pandemic with notably less enrolled patients than a data review committee had previously recommended to the Individual Defendants. Indeed,

as stated in the *New England Journal of Medicine* paper that was published on April 7, 2022, a data review committee performed a “blinded reassessment of the sample size after response data were available from 70% of the patients at the test-of-cure visit to confirm the initial sample-size estimate as adequate or to recommend an increase in sample size to ensure adequate power for measurement of the primary endpoint.” After conducting this reassessment, the data review committee “recommended[ed] an increase in sample size to ensure adequate power for measurement of the primary endpoint.” In particular, the *New England Journal of Medicine* paper stated that “The data review committee recommended enrollment up to the protocol-allowed maximum of 1,450 patients,” but the Individual Defendants nonetheless chose to keep the lower enrollment of 1,372 patients. In other words, the Individual Defendants were made aware of the strong possibility that a lower patient enrollment could negatively affect the ADAPT-PO Trial’s ability to provide accurate and robust data up to the FDA’s standards, but still chose to narrow the margin for error and unnecessarily increase the risk of failure.

313. Additionally, the Individual Defendants had extraordinary channels of communication with the FDA both before the Tebipenem HBr NDA submission and during the FDA’s review of the NDA. Indeed, as early as March 29, 2019, over a year and a half before the beginning of the Relevant Period, the Individual Defendants represented to investors that the FDA had granted Tebipenem HBr Fast Track Designation, which gave Spero the ability to interact with the FDA more frequently to expedite the FDA’s review of Tebipenem HBr. In other words, the Individual Defendants were afforded unusual access to the FDA both before and after Tebipenem HBr’s submission. Similarly, one of the confidential witnesses from the Securities Class Action characterized the Fast Track Designation as the FDA “hold[ing] your hand through the whole (process).”

314. The Individual Defendants’ public statements reveal that the Company had numerous opportunities to address concerns regarding the inclusion of gram-positive patients in the ADAPT-PO Trial and the overall number of patients included in the ADAPT-PO Trial. For example, in September 2020, Defendant Mahadevia touted that Spero had “pre-NDA meetings” with the FDA in the future. By March 2021, the Individual Defendants stated that: (1) Spero had had at least one pre-NDA meeting with the FDA that had addressed “the format and content of the planned data package” that would form part of the Tebipenem HBr NDA; and (2) that the Individual Defendants had “received feedback” from the FDA. By September 2021, Defendant Mahadevia boasted that Spero had “multiple” meetings with the FDA addressing the crucial issue of whether ADAPT-PO Trial data results could be used for a Tebipenem HBr NDA. Additionally, by December 2021, Spero had received “a lot of comments back from the FDA - requests for additional information on various topics: clinical, non-clinical, CMC [Chemistry, Manufacturing, and Control]. That continued through December, January and February – that was the peak. *[Spero] got questions from [the FDA] just about every week, even a couple times a week.*” Moreover, according to CW2, Spero “got so many questions,” and “a lot of them were clinical.” CW2 also stated that *the number of questions the FDA submitted to Spero was much higher than normal in CW2’s twenty years of experience in working in the drug development industry.*

315. By March 2022, the Individual Defendants chose to keep even their own employees in the dark about the “deficiencies” in the Tebipenem HBr NDA. According to three confidential witnesses, CW3, CW4, and CW6, the Individual Defendants would not inform their own employees about the nature of the deficiencies. CW3 stated they “did not want to comment on what it was.” CW6 stated the Individual Defendants “kept it very close to the vest.” CW4 went further, stating that *“They knew details of the deficiencies, but they were not going to share it.*

They didn't let you know if it was regarding the research, the manufacturing, nothing. ***There was no indication of what it could have been.***"

316. By the beginning of April 2022, the Individual Defendants actively determined to hide the truth from Spero's own employees. Indeed, Jennifer Liscouski, Spero's VP of Regulatory Affairs, acting on orders from Spero's "leadership team," instructed CW2 to prevent Company employees from accessing the files Spero submitted to the FDA, cutting off access to all employees except for Defendant Mahadevia one C-suite executive, three regulatory affairs employees, one of which was CW2 herself.

317. After actively hiding the truth from the public and even their own employees, the Individual Defendants set in place a covert plan to terminate 75% of Spero's employees after the Company's late cycle meeting with the FDA on a Thursday in late April 2022. Just five days later, on the following Tuesday after the meeting with the FDA, severance payments were already sent to 75% of Spero's employees, who were abruptly terminated, without notice, that day. A sudden layoff of that size could not have been accomplished without significant pre-planning and communication between multiple departments across the Company, including top leadership, payroll, and accounting. Tellingly, CW6 noted that "***Those plans had to be well under way to just pull the plug on all of us. It takes time to law that (action) out and run the numbers.***"

DAMAGES TO SPERO

318. As a direct and proximate result of the Individual Defendants' conduct, Spero has lost and expended, and will continue to lose and expend, many millions of dollars.

319. Such expenditures include, but are not limited to, legal fees associated with the Securities Class Action filed against the Company and two of the Individual Defendants, and amounts paid to outside lawyers, accountants, and investigators in connection thereto.

320. Such losses include, but are not limited to, compensation and benefits paid to Individual Defendants who breached their fiduciary duties to the Company, including bonuses tied to the Company's attainment of certain objectives, and benefits paid to the Individual Defendants who breached their fiduciary duties to the Company.

321. Further, the Company has expended and will continue to expend costs in connection with restructuring its business operations and as a result of Spero's workforce reductions.

322. As a direct and proximate result of the Individual Defendants' conduct, Spero has also suffered and will continue to suffer a loss of reputation and goodwill, and a "liar's discount" that will plague the Company's stock in the future due to the Company's and their misrepresentations and the Individual Defendant's breaches of fiduciary duties and unjust enrichment.

DERIVATIVE ALLEGATIONS

323. Plaintiffs bring this action derivatively and for the benefit of Spero to redress injuries suffered, and to be suffered, as a result of the Individual Defendants' breaches of their fiduciary duties as directors and/or officers of Spero, unjust enrichment, waste of corporate assets, and violations of Section 14(a) of the Exchange Act, as well as the aiding and abetting thereof, and for contribution under Sections 10(b) and 21D of the Exchange Act.

324. Spero is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

325. Plaintiffs are, and have been at all relevant times, shareholders of Spero. Plaintiffs will adequately and fairly represent the interests of Spero in enforcing and prosecuting its rights, and, to that end, have retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

DEMAND FUTILITY ALLEGATIONS

326. Plaintiffs incorporate by reference and re-allege each and every allegation stated above as if fully set forth herein.

327. A pre-suit demand on the Board of Spero is futile and, therefore, excused. At the time of filing of this action, the Board consists of the following eight individuals: Defendants Mahadevia, Deshpande, Jackson, Pottage, Smith, Thomas, and Vink (the “Director Defendants”), along with non-party Kathleen Tregoning (together with the Director Defendants, the “Directors”). Plaintiffs need only to allege demand futility as to four of eight Directors who are on the Board at the time this action is commenced.

328. Demand is excused as to all of the Director Defendants because each one of them faces, individually and collectively, a substantial likelihood of liability as a result of the scheme they engaged in knowingly or recklessly to make and/or cause the Company to make false and misleading statements and omissions of material facts. Furthermore, while the price of the Company’s stock was artificially inflated by their misconduct, one of the Director Defendants further breached his fiduciary duties by engaging in insider sales of the Company’s common stock, which caused him to receive over \$471,518 in proceeds, and which further demonstrates his motive for facilitating and participating in the scheme. All of the above renders the Director Defendants unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

329. In complete abdication of their fiduciary duties, the Director Defendants either knowingly or recklessly participated in making the materially false and misleading statements alleged herein. The fraudulent scheme was, *inter alia*, intended to make the Company appear more profitable and attractive to investors. As a result of the foregoing, the Director Defendants breached

their fiduciary duties, face a substantial likelihood of liability, are not disinterested or independent, and demand upon them is futile, and thus excused.

330. Additional reasons that demand on Defendant Mahadevia is futile follow. Defendant Mahadevia currently serves as the Chairman of the Board and has served as a Company director since September 2013. He also served as the Company's CEO and President from March 2015 until August 2023. As such, the Company provided Defendant Mahadevia with his principal occupation during the Relevant Period for which he received lucrative compensation. Thus, as the Company admits, he is a non-independent director. As CEO and President throughout the Relevant Period, Defendant Mahadevia was ultimately responsible for all of the false and misleading statements and omissions that were made by or on behalf of the Company, including, *inter alia*, those contained in SEC filings and his statements in press releases, earnings calls, and conferences wherein he personally made the false and misleading statements at issue. Moreover, Defendant Mahadevia signed, and thus personally made, the false and misleading statements in the 2021 10-K and 2022 10-K that are referenced herein. He also solicited the 2020 and 2021 Proxy Statements, which contained material misrepresentations and omissions and contributed to his re-election to the Board. As the Company's highest officer and a trusted director, he conducted little, if any, oversight of the Company's engagement in the scheme and consciously disregarded his duties to protect corporate assets. Moreover, his insider sales made before the fraud was exposed yielded approximately \$471,518 in proceeds and demonstrate his motive in facilitating and participating in the scheme. Furthermore, Defendant Mahadevia is a defendant in the Securities Class Action. For these reasons, too, Defendant Mahadevia breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

331. Additional reasons that demand on Defendant Shukla is futile follow. Defendant Shukla has served as the Company's CEO, President, and as a director since August 1, 2023. Previously, he served as the Company's CFO from January 2021 until August 1, 2023. As such, the Company provides Defendant Shukla with his principal occupation for which he receives lucrative compensation, including \$2,228,271 for the 2021 Fiscal Year and \$1,673,070 for the 2022 Fiscal Year. Thus, as the Company admits, he is a non-independent director. As CFO throughout the Relevant Period, Defendant Shukla was ultimately responsible for all of the false and misleading statements and omissions that were made by or on behalf of the Company, including, *inter alia*, those contained in SEC filings and his statements in press releases, earnings calls, and conferences wherein he personally made the false and misleading statements at issue. Moreover, Defendant Shukla signed, and thus personally made, the false and misleading statements in the 2021 10-K and the 2022 10-K that are referenced herein. As one of the Company's highest officers and a trusted director, he conducted little, if any, oversight of the Company's engagement in the scheme and consciously disregarded his duties to protect corporate assets. Furthermore, Defendant Shukla is a defendant in the Securities Class Action. For these reasons, too, Defendant Shukla breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

332. Additional reasons that demand on Defendant Deshpande is futile follow. Defendant Deshpande has served as a Company director since January 2014 and served as Chairman of the Board from January 2014 until August 1, 2023. He also serves as Chair of the Nominating and Corporate Governance Committee and as a member of the Compensation Committee. Defendant Deshpande received and continues to receive handsome compensation for

his role as a director as noted above. As a trusted Company director, he conducted little, if any, oversight of the Company's engagement in the scheme to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Deshpande signed, and thus personally made, the false and misleading statements in the 2021 10-K and 2022 10-K that are referenced herein. He also solicited the 2020 and 2021 Proxy Statements, which contained material misrepresentations and omissions and contributed to his re-election to the Board, as alleged above. For these reasons, too, Defendant Deshpande breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and therefore, excused.

333. Additional reasons that demand on Defendant Jackson is futile follow. Defendant Jackson has served as a Company director since April 2020 and serves as a member of the Audit Committee and the Nominating and Corporate Governance Committee. Defendant Jackson received and continues to receive handsome compensation for his role as a director as noted above. As a trusted Company director, he conducted little, if any, oversight of the Company's engagement in the scheme to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Jackson signed, and thus personally made, the false and misleading statements in the 2021 10-K and 2022 10-K that are referenced herein. He also solicited the 2020 and 2021 Proxy Statements, which contained material misrepresentations and omissions and contributed to his re-election to the Board, as alleged above. For these reasons, too, Defendant Jackson breached his fiduciary duties, faces a substantial

likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and therefore, excused.

334. Additional reasons that demand on Defendant Pottage is futile follow. Defendant Pottage has served as a Company director since September 2018 and serves as a member of the Audit Committee. Defendant Pottage received and continues to receive compensation for his role as a director as noted above. As a trusted Company director, he conducted little, if any, oversight of the Company's engagement in the scheme to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Pottage signed, and thus personally made, the false and misleading statements in the 2021 10-K and 2022 10-K that are referenced herein. He also solicited the 2020 and 2021 Proxy Statements, which contained material misrepresentations and omissions and contributed to his re-election to the Board, as alleged above. For these reasons, too, Defendant Pottage breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and therefore, excused.

335. Additional reasons that demand on Defendant Smith is futile follow. Defendant Smith has served as a Company director since March 2019 and serves as a member of the Compensation Committee. Defendant Smith received and continues to receive compensation for her role as a director as noted above. As a trusted Company director, she conducted little, if any, oversight of the Company's engagement in the scheme to make false and misleading statements, consciously disregarded her duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded her duties to protect corporate assets. Moreover, Defendant Smith signed, and thus personally made, the false and misleading statements in the 2021 10-K and

2022 10-K that are referenced herein. She also solicited the 2020 and 2021 Proxy Statements, which contained material misrepresentations and omissions and contributed to her re-election to the Board, as alleged above. For these reasons, too, Defendant Smith breached her fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon her is futile and therefore, excused.

336. Additional reasons that demand on Defendant Thomas is futile follow. Defendant Thomas has served as a Company director since July 2017 and serves as the Chair of the Audit Committee and as a member of the Nominating and Corporate Governance Committee. Defendant Thomas received and continues to receive compensation for his role as a director as noted above. As a trusted Company director, he conducted little, if any, oversight of the Company's engagement in the scheme to make false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Thomas signed, and thus personally made, the false and misleading statements in the 2021 10-K and 2022 10-K that are referenced herein. He also solicited the 2020 and 2021 Proxy Statements, which contained material misrepresentations and omissions, as alleged above. For these reasons, too, Defendant Thomas breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and therefore, excused.

337. Additional reasons that demand on Defendant Vink is futile follow. Defendant Vink has served as a Company director since September 2015 and serves as the Chair of the Compensation Committee and as a member of the Audit Committee. Defendant Vink received and continues to receive compensation for his role as a director as noted above. As a trusted Company director, he conducted little, if any, oversight of the Company's engagement in the scheme to make

false and misleading statements, consciously disregarded his duties to monitor such controls over reporting and engagement in the scheme, and consciously disregarded his duties to protect corporate assets. Moreover, Defendant Vink signed, and thus personally made, the false and misleading statements in the 2021 10-K and 2022 10-K that are referenced herein. He also solicited the 2020 and 2021 Proxy Statements, which contained material misrepresentations and omissions, as alleged above. For these reasons, too, Defendant Vink breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and therefore, excused.

338. Additional reasons that demand on the Board is futile follow.

339. As described above, Defendant Mahadevia directly engaged in insider trading, in violation of federal law. While in possession of material non-public information, Defendant Mahadevia received proceeds in excess of \$471,518 as a result of insider transactions executed during the period when the Company's stock price was artificially inflated due to the false and misleading statements alleged herein. Therefore, demand in this case is futile as to him, and further excused.

340. Additionally, the Directors have longstanding business and personal relationships with each other and the Individual Defendants that preclude them from acting independently and in the best interests of the Company and the shareholders. These conflicts of interest precluded the Directors from adequately monitoring the Company's operations and internal controls and calling into question the Individual Defendants' conduct.

341. Demand on the Directors is also futile because they will benefit in the future from the Individual Defendants' solicitation of the 2021 Proxy Statement which called for shareholder approval of the Plan Proposal. The Plan Proposal called for a shareholder vote to increase the

number of shares to be issued pursuant to the 2017 Stock Incentive Plan by 3,200,000, thereby allowing the Individual Defendants to continue to be able to receive payments under the Plan in the future. Shareholders would not have approved the Plan Proposal had they known the true state of affairs at the Company. As a result, the Directors cannot be presumed to be disinterested in taking action against those who solicited the materially false and misleading 2021 Proxy Statement (i.e. Defendants Deshpande, Smith, Vink, Thomas, Pottage, Formela, and Jackson). As such, demand upon the Directors is futile and, therefore, excused.

342. Defendants Vink, Smith and Deshpande served as members of the Compensation Committee (the “Compensation Committee Directors”) during the Relevant Period. The Compensation Committee Directors solicited shareholder approval of the Plan Proposal, which granted them the right to continue to determine how many shares of Company common stock to administer under the Plan to executives and non-employee directors, including themselves. They all stood to benefit from shareholder approval of the Plan Proposal, which allowed for more Company shares to be issued to officers and directors pursuant to the Plan and which Company shareholders were deceived into approving while the Individual Defendants made false and misleading statements. Thus, the Directors were beholden to the Compensation Committee Directors, and the Compensation Committee Directors were beholden to each other, because they would not take action against the very directors who held the authority to award them high compensation pursuant to the Plan. These conflicts of interest precluded the Compensation Committee Directors and the rest of the Directors from calling into question the Director Defendants and other Individual Defendants’ conduct. Thus, demand upon the Compensation Committee Directors would be futile.

343. Defendants Thomas (as Chair), Jackson, Pottage, and Vink (the “Audit Committee Defendants”) served on the Company’s Audit Committee during the Relevant Period. The Audit Committee Defendants violated the Audit Committee Charter by engaging in or permitting the scheme to cause the Company to making false and misleading statements to the investing public, and to facilitate and disguise the Individual Defendants’ violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, and/or violations of the Exchange Act. In addition, the Audit Committee Defendants violated the Audit Committee Charter by failing to adequately oversee the integrity of the Company’s financial disclosures, failing to adequately oversee the Company’s compliance with legal and regulatory requirements, failing to adequately oversee the Company’s risk assessments and risk management, failing to adequately discuss with management the Company’s information prior to public distribution, and failing to adequately oversee the Company’s disclosure controls and procedures. Thus, the Audit Committee Defendants breached their fiduciary duties, are not disinterested, and demand is excused as to them.

344. In violation of the Code of Conduct, the Director Defendants engaged in or permitted the scheme to cause the Company to issue materially false and misleading statements to the investing public, and to facilitate and disguise the Individual Defendants’ violations of law, including breaches of fiduciary duty, unjust enrichment, waste of corporate assets, and violations of the Exchange Act. In addition, the Individual Defendants violated the Code of Conduct by failing to act with integrity, supporting and profiting from unethical behavior, failing to avoid conflicts of interest, engaging in insider trading, failing to ensure the Company’s disclosures were accurate, failing to ensure the Company complied with applicable laws, rules, and regulations, and failing to promptly report known violations of the Code of Conduct and the law. Thus, the Director

Defendants breached the Company's own Code of Conduct, are not disinterested, and demand is excused as to them.

345. Spero has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Directors have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for Spero any part of the damages Spero suffered and will continue to suffer thereby. Thus, any demand upon the Directors would be futile.

346. The acts complained of herein constitute violations of fiduciary duties owed by Spero's officers and directors, and these acts are incapable of ratification.

347. The Individual Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Director Defendants can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the Directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein and cannot be presumed to be capable of exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

348. The Director Defendants may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds, i.e., monies belonging to the stockholders of Spero. If there is a directors' and officers' liability insurance policy covering the Directors, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Directors, known as, *inter alia*, the

“insured-versus-insured exclusion.” As a result, if the Director Defendants were to sue themselves or certain of the officers of Spero, there would be no directors’ and officers’ insurance protection. Accordingly, the Director Defendants cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Director Defendants is futile and, therefore, excused.

349. If there is no directors’ and officers’ liability insurance, then the Director Defendants will not cause Spero to sue the Individual Defendants named herein, because, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event, as well.

350. Thus, for all of the reasons set forth above, all of the Director Defendants, and, if not all of them, at least four of the Directors cannot consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

FIRST CLAIM

Against Individual Defendants for Violations of Section 14(a) of the Exchange Act

351. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above, as though fully set forth herein.

352. Section 14(a) of the Exchange Act provides that “[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent

or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l].”

353. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. § 240.14a-9.

354. Under the direction and watch of Defendants Mahadevia, Deshpande, Jackson, Pottage, Smith, Thomas, Formela, and Vink, the 2020 and 2021 Proxy Statements failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval; (3) Spero faced an unusually high amount of questions and inquiries from the FDA before and after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company’s workforce and a shift in the Company’s focus; (6) due to the foregoing, Spero’s reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed to maintain adequate internal controls.

355. Under the direction and watch of Defendants Mahadevia, Deshpande, Jackson, Pottage, Smith, Thomas, Formela, and Vink, the 2020 and 2021 Proxy Statements failed to disclose, *inter alia*, that: (1) contrary to the 2020 and 2021 Proxy Statements’ descriptions of the

Board's and its committees' risk oversight functions, the Board and its committees were not adequately exercising these functions and were causing or permitting the Company to issue false and misleading statements; (2) the Individual Defendants were violating the Code of Conduct without obtaining waivers or else without such waivers being disclosed; and (4) the Individual Defendants, including those soliciting the 2020 and 2021 Proxy Statements, were breaching their fiduciary duties to the Company and its shareholders and were thus improperly interested in receiving unjust compensation under the Plan, not merely seeking to obtain and retain the services of qualified individuals.

356. In the exercise of reasonable care, Defendants Mahadevia, Deshpande, Jackson, Pottage, Smith, Thomas, and Vink knew or should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2020 and 2021 Proxy Statements were materially false and misleading. The misrepresentations and omissions were material to Plaintiffs in voting on the matters set forth for shareholder determination in the 2020 and 2021 Proxy Statements, including but not limited to, the election of directors, the approval of the Plan Proposal, and the approval of an amendment to Spero's Amended and Restated Certificate of Incorporation to increase the total number of shares of common stock authorized for issuance thereunder from 60,000,000 shares to 120,000,000 shares.

357. The false and misleading elements of the 2020 Proxy Statement led Company shareholders to, *inter alia*, (1) elect Defendants Mahadevia and Deshpande to the Board, allowing them to continue to breach their fiduciary duties to the Company; and (2) ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2020.

358. The false and misleading elements of the 2021 Proxy Statement led Company shareholders to, *inter alia*, (1) elect Defendants Jackson, Pottage, and Smith to the Board, allowing them to continue to breach their fiduciary duties to the Company; (2) ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2021; (3) approve the Plan Proposal; and (4) approve an amendment to Spero's Amended and Restated Certificate of Incorporation to increase the total number of shares of common stock authorized for issuance thereunder from 60,000,000 shares to 120,000,000 shares.

359. The Company was damaged as a result of Defendants Mahadevia, Deshpande, Jackson, Pottage, Smith, Thomas, and Vinks' material misrepresentations and omissions in the 2020 and 2021 Proxy Statements.

360. Plaintiffs on behalf of Spero have no adequate remedy at law.

SECOND CLAIM

Against Individual Defendants for Breach of Fiduciary Duties

361. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above, as though fully set forth herein.

362. Each Individual Defendant owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Spero's business and affairs.

363. Each of the Individual Defendants violated and breached his or her fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

364. The Individual Defendants' conduct set forth herein was due to their intentional or reckless breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual Defendants intentionally or recklessly breached or disregarded their fiduciary duties to protect the rights and interests of Spero.

365. In breach of their fiduciary duties owed to Spero, the Individual Defendants willfully or recklessly made false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) the ADAPT-PO Trial lacked a sufficiently evaluable patient population to make FDA approval viable; (2) the ADAPT-PO Trial failed to generate data demonstrating that Tebipenem HBr could meet the pre-specified non-inferiority margin of -12.5% compared to IV ertapenem that was necessary for FDA approval; (3) Spero faced an unusually high amount of questions and inquiries from the FDA before and after the NDA submission; (4) as a result of the foregoing, the FDA would not approve the Tebipenem HBr NDA; (5) due to the foregoing, Spero would undergo a business restructure resulting in the sacking of 75% of the Company's workforce and a shift in the Company's focus; (6) due to the foregoing, Spero's reported revenue, net loss, direct research and development expenses and government contract payments were artificially inflated; and (7) the Company failed to maintain adequate internal controls.

366. As a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

367. The Individual Defendants also failed to correct and caused the Company to fail to correct the false and misleading statements and omissions of material fact, rendering them personally liable to the Company for breaching their fiduciary duties.

368. Also in breach of their fiduciary duties, the Individual Defendants failed to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls.

369. In yet further breach of their fiduciary duties, during the Relevant Period, Defendant Mahadevia engaged in numerous insider sales, netting proceeds of approximately

\$471,518, while the price of the Company's common stock was artificially inflated due to the false and misleading statements of material fact discussed herein.

370. The Individual Defendants had actual or constructive knowledge that the Company issued materially false and misleading statements, and they failed to correct the Company's public statements and representations. The Individual Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth, in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and omissions were committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of the Company's securities and disguising insider sales.

371. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly engage in the fraudulent scheme set forth herein and to fail to maintain internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent scheme set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent scheme and to fail to maintain adequate internal controls, even though such facts were available to them. Such improper conduct was committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of the Company's securities. The Individual Defendants, in good faith, should have taken appropriate action to correct the scheme alleged herein and to prevent it from continuing to occur.

372. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

373. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Spero has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

374. Plaintiffs on behalf of Spero have no adequate remedy at law.

THIRD CLAIM

Against Individual Defendants for Unjust Enrichment

375. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above, as though fully set forth herein.

376. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Spero.

377. The Individual Defendants either benefitted financially from the improper conduct and their making insider sales, or received profits, bonuses, stock options, or similar compensation from Spero that was tied to the performance or artificially inflated valuation of Spero, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.

378. Plaintiffs, as shareholders and representatives of Spero, seek restitution from the Individual Defendants and seek an order from this Court disgorging all profits, including from insider transactions, benefits, and other compensation, including any performance-based or valuation-based compensation—obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.

379. Plaintiffs on behalf of Spero have no adequate remedy at law.

FOURTH CLAIM

Against Individual Defendants for Waste of Corporate Assets

380. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above, as though fully set forth herein.

381. As a further result of the foregoing, the Company will incur many millions of dollars of legal liability and/or costs to defend unlawful actions, to engage in internal investigations, and to lose financing from investors and business from future customers who no longer trust the Company and its products.

382. As a result of the waste of corporate assets, the Individual Defendants are each liable to the Company.

383. Plaintiffs on behalf of Spero have no adequate remedy at law.

FIFTH CLAIM

Against Individual Defendants for Abuse of Control

384. Plaintiffs incorporate by reference and reallege each and every allegation set forth above, as though fully set forth herein.

385. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Spero, for which they are legally responsible.

386. As a direct and proximate result of the Individual Defendants' abuse of control, Spero has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

387. Plaintiffs on behalf of Spero have no adequate remedy at law.

SIXTH CLAIM

Against Individual Defendants for Gross Mismanagement

388. Plaintiffs incorporate by reference and reallege each and every allegation set forth above, as though fully set forth herein.

389. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Spero in a manner consistent with the operations of a publicly held corporation.

390. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Spero has sustained and will continue to sustain significant damages.

391. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

392. Plaintiffs on behalf of Spero have no adequate remedy at law.

SEVENTH CLAIM

Against Defendants Mahadevia and Shukla for Contributions Under Sections 10(b) and 21D of the Exchange Act

393. Plaintiffs incorporate by reference and reallege each and every allegation set forth above, as though fully set forth herein.

394. Spero and Defendants Mahadevia and Shukla are named as defendants in the Securities Class Action, which asserts claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Action for these violations of the federal securities laws, the Company's liability will be in whole or in part due to Defendants Mahadevia's and Shukla's willful and/or reckless violations of their obligations as officers and/or directors of Spero.

395. Defendants Mahadevia and Shukla, because of their positions of control and authority as officers and/or directors of Spero, were able to and did, directly and/or indirectly,

exercise control over the business and corporate affairs of Spero, including the wrongful acts complained of herein and in the Securities Class Action.

396. Accordingly, Defendants Mahadevia and Shukla are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

397. As such, Spero is entitled to receive all appropriate contribution or indemnification from Defendants Mahadevia and Shukla.

PRAYER FOR RELIEF

FOR THESE REASONS, Plaintiffs demand judgment in the Company's favor against all Individual Defendants as follows:

(a) Declaring that Plaintiffs may maintain this action on behalf of Spero, and that Plaintiffs are adequate representatives of the Company;

(b) Declaring that the Individual Defendants have breached or aided and abetted the breach of their fiduciary duties to Spero;

(c) Determining and awarding to Spero the damages sustained by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest thereon;

(d) Directing Spero and the Individual Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Spero and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Certificate of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies:

1. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the board;

2. a provision to permit the shareholders of Spero to nominate at least four candidates for election to the Board; and

3. a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations.

(e) Awarding Spero restitution from Individual Defendants, and each of them;

(f) Awarding Plaintiffs the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

(g) Granting such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Dated: October 11, 2023

Respectfully submitted,

Of Counsel:

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